EXHIBIT Z
(Filed Under Seal)

EXHIBIT AA

G2™ FILTER SYSTEM

for Permanent Placement

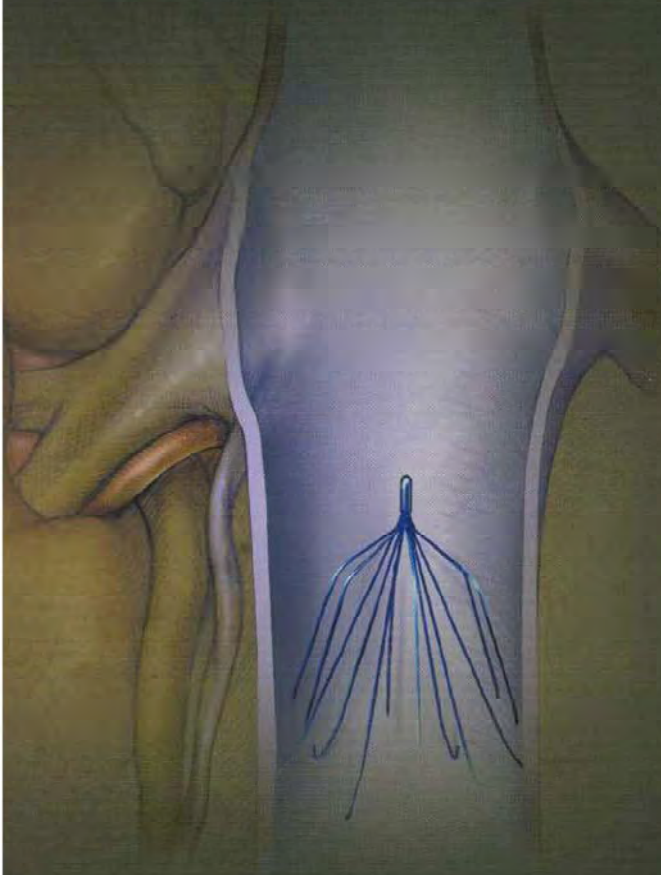
BARD PERIPHERAL VASCULAR

INTRODUCING THE

G2™

VENA CAVA FILTER

for Permanent Placement



The G2™ Filter combines the **best design features** of Bard's existing vena cava filters to create a **brand-new permanent filter platform** — taking strength and stability to a new level.

- Increased **MIGRATION RESISTANCE***
- **IMPROVED CENTERING***
- Enhanced **FRACTURE RESISTANCE***

The newly enhanced G2™ Filter continues the Bard tradition of filter **INNOVATION** spanning over a decade.

* Data on File

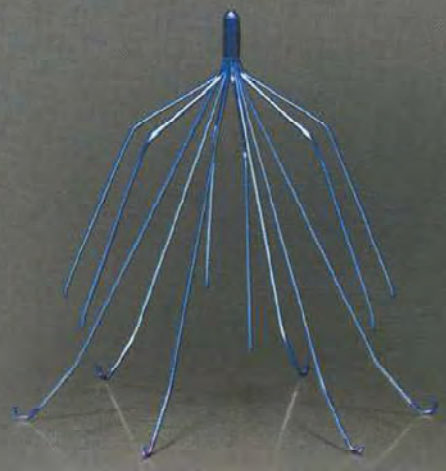
TIMELESS PE

CLOT TRAPPING & CAVAL PATENCY

G2™ Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

LOW-PROFILE

7F delivery system is the lowest profile of any conical filter on the market.



SECURE FIXATION

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2™ Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm
Data on File

SELF-CENTERING

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

RFORMANCE

G2™ FILTER SYSTEM

for Permanent Placement

ORDER INFORMATION

Catalog No.	Description
RF-310F	G2™ Filter System — Femoral Delivery Kit

PHYSICIAN'S SIGNATURE

For more information, contact:

Bard Peripheral Vascular, Inc.
P. O. Box 1740
Tempe, AZ 85280-1740
USA

Tel: 1-480-894-9515
1-800-321-4254
Fax: 1-480-966-7062
1-800-440-5376
www.bardpv.com

The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

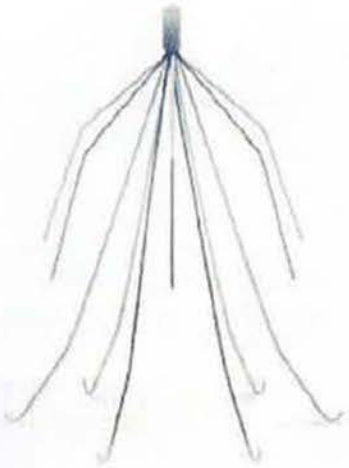
BARD PERIPHERAL VASCULAR

EXHIBIT BB

RECOVERY Cone' Removal System

RECOVERY® Timeless Performance[1]

RECOVERY® Filter's unique self-centering design, proven conical shape and bi-level filtering system create the ideal balance between clot trapping efficiency and caval patency. Advanced design and accurate placement coupled with lasting performance make RECOVERY® the permanent solution for caval interruption.



Low Profile

- At 7F, RECOVERY® Filter's delivery system has one of the lowest profiles of any filter on the market.

Clot Trapping and Caval Patency

- The RECOVERY® Filter utilizes the proven conical filter shape arranged into two offset layers to create a filtration system that effectively traps large and small emboli without compromising caval patency.

Self-Centering

- Articulated arms, along with the specially engineered flexible pusher wire of the delivery system, promote a centered placement.

Latest Advance in Filter Technology

- The RECOVERY® Filter, a product of Bard's industry-leading nitinol experience, incorporates the best features of today's most advanced caval filtration devices while overcoming the disadvantages with older designs.

Secure Fixation

- Filter hooks are loaded into a delivery system that is specifically constructed to prevent leg crossing.

DEPOSITION EXHIBIT 21

PENGAD 800-631-6989

Recovery Cone® Removal System for use with the Recovery® Filter and Foreign Body Retrievals

ENGLISH

Instructions for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

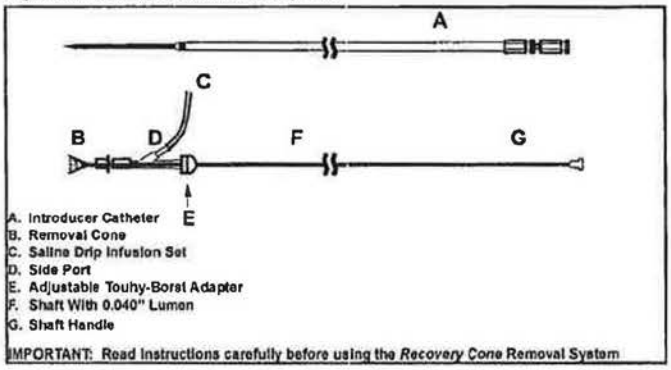
The ***Recovery Cone*** Removal System is intended to percutaneously remove the ***Recovery*** Filter or a foreign body as indicated.

The cone is designed to advance through its 75 cm, 10 French I.D. introducer catheter using a flexible, Pebax shaft. A reinforced cone at the end of the shaft is designed to collapse over the tip of the ***Recovery*** Filter or a foreign body for percutaneous removal. This cone is reinforced by a wire basket. The introducer sheath has a radiopaque marker for enhanced visualization. The introducer sheath is used to collapse the removal cone over the ***Recovery*** Filter tip or a foreign body and pull the collapsed cone into the sheath to remove the Filter or foreign body.

B. Device Description

The ***Recovery Cone*** Removal System consists of the ***Recovery Cone*** and Introducer Catheter (Figure A). The cone consists of a reinforced urethane cone, 15-mm in diameter. The cone is connected to a plastic (Pebax) shaft and handle. The shaft has a central lumen that accommodates a 0.035" guidewire. A Touhy-Borst Y-adapter is used to connect the cone to the Introducer Catheter and to a saline flush or drip. The Introducer Catheter consists of a 10 French I.D. introducer sheath and dilator. The introducer sheath has a radiopaque marker for enhanced fluoroscopic visualization.

Figure A. *Recovery Cone* Removal System



A. Introducer Catheter
B. Removal Cone
C. Saline Drip Infusion Set
D. Side Port
E. Adjustable Touhy-Borst Adapter
F. Shaft With 0.040" Lumen
G. Shaft Handle

IMPORTANT: Read instructions carefully before using the *Recovery Cone* Removal System

C. Indications for Use

The ***Recovery Cone*** Removal System is intended for use to percutaneously remove the ***Recovery*** Filter or facilitate the retrieval of foreign objects from the peripheral vascular system.

D. Contraindications for Use

None known.

E. Warnings

- Do not attempt to remove the ***Recovery*** Filter if significant amounts of thrombus are trapped within the Filter or if the Filter tip is embedded within the vena caval wall.
- Do not use excessive force when manipulating the cone. Excessive force may damage the catheter or other parts of the Recovery Cone.
- When attempting to retrieve a ***Recovery*** Filter, only use the ***Recovery Cone*** Removal System. Use of other devices has resulted in recurrent pulmonary embolism.
- Ensure adequate clearance in small vessels before deploying the ***Recovery Cone***.
- Withdrawal of large foreign bodies may require a cut-down at the peripheral site.
- If resistance is experienced during the retrieval procedure, check the captured Filter or foreign body and introducer sheath using fluoroscopy.
- Contents are supplied sterile. Do not use if sterile barrier is damaged. If damage is found, contact your Bard representative.
- Single Patient Use Only. Do not reuse, reprocess or resterilize.
- Do not use the device or accessories after the expiration date.

F. Precautions

- Anatomical variances may complicate insertion and deployment of the device. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemplating removing the ***Recovery*** Filter or a foreign body from the inferior vena cava with the ***Recovery Cone*** Removal System in patients with significant kyphoscoliotic spinal deformations because the vessel may follow the general course of such anatomic deformations. This may require advanced techniques to remove the Filter or foreign body.
- After use, the ***Recovery Cone*** Removal System and its accessories and insertions supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.
- The size and location of the foreign body may impact its ability to be successfully captured and retrieved.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications.
Possible complications of ***Recovery Cone*** usage include, but are not limited to, the following:

- Pulmonary Embolism
- Embolization
- Damage to the artery or vein
- Vessel tear or disruption
- Device entrapment
- Hematoma at the access site
- Infection
- Stroke

NOTE: It is possible that complications such as those described in the "Warnings, Precautions and Potential Complications" section of this IFU may affect the recoverability of the device or foreign body and result in the clinician's decision to have the device or foreign body remain permanently implanted.

H. Equipment Required

The following equipment is required for use:

- ***Recovery Cone*** Removal System that contains:
  - One 75 cm, 10 French I.D. delivery sheath and dilator set
  - One Y-adapter with ***Recovery Cone*** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

I. Clinical Experience with Recovery Filter

The ***Recovery*** Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 Filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with Filters in place of causes unrelated to Filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days (see histogram).

Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein jugular (n=1). One was removed surgically during a cancer operation where the mass was impinging on the Filter. The two methods described in the Instructions for Use were used to retrieve the Filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the ***Recovery Cone*** System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other adverse event reported was a fractured Filter arm and hook. This Filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The Filter was retrieved, minus the hook.

Clinical Experience Summary Table	
Recovery Filters Implanted	58
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	8-89 years (52 years average)
Reason for Filter Placement	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	3
Prophylaxis	2
Time to removal	1-161 days (60 days average)
Follow-up post-removal	1-901 days (325 average)
Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1
Asymptomatic pulmonary embolism post-removal	1

J. Directions for Use – *Recovery* Filter Removal
(See Section K for Foreign Body Retrieval Directions for Use)

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone***® Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the ***Recovery***® Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the Filter. If there is significant thrombus within the Filter, do not remove the ***Recovery*** Filter.

***Recovery Cone* Insertion and Delivery**

11. Remove the cone and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and Filter delivery system should be held in a straight line to minimize friction.
16. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
17. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the shaft and retracting the catheter.

Capture of *Recovery* Filter
***Recovery* Filter Removal**

18. The capture of the ***Recovery*** Filter is illustrated in ***Recovery*** Filter Removal - Figures A-E:

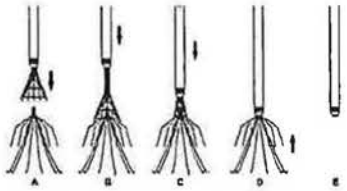


Figure A: After the cone has been opened superior to the Filter, advance the cone over the Filter by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the Filter tip.

Figure B: Close the cone over the Filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the Filter, remove the Filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The Filter has been retracted into the catheter.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed after withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***Recovery*** Filter, guidewire assisted techniques may be used.

Use of a Guidewire

If it is difficult to advance the ***Recovery Cone*** System over the ***Recovery*** Filter tip, one may use a guidewire to facilitate advancement of the cone.
Withdraw the introducer sheath and cone shaft away from the Filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the Filter near the Filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the Filter tip, advance the cone over the guidewire to the Filter tip.

Advance the introducer sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 18.

K. Directions for Use – Foreign Body Retrieval

1. Select a suitable entry site to access the foreign body.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform puncture with an 18 gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the foreign body.
6. Remove the entry needle over the guidewire.
7. Pre-dilate the insertion site with a 12F dilator and then advance the introducer catheter together with its tapered dilator over the guidewire to the target area.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

8. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently with saline to maintain introducer catheter patency.
9. Remove the cone and pusher system from Kit B.
10. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
11. Slowly withdraw the cone into the Y-adapter to collapse the cone

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

12. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
13. Attach the Y-adapter with the collapsed cone to the introducer catheter.
14. Advance the cone by moving the pusher shaft forward through the introducer catheter.
15. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter.
16. Open the cone by stabilizing the shaft and retracting the catheter
17. After the cone has been opened adjacent to the foreign body, advance the cone over foreign body by holding the introducer catheter stationary and advancing the pusher shaft.
18. Close the cone over the foreign body by advancing the introducer catheter over the cone while holding the pusher shaft stationary.
19. Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
20. With the cone collapsed over the foreign body, remove the foreign body by stabilizing the introducer catheter and retracting the pusher shaft in one smooth, continuous motion.

L. How Supplied

Each ***Recovery Cone*** Removal System is supplied preloaded. Each ***Recovery Cone*** Removal System is sterile and non-pyrogenic unless package has been opened or damaged, and is ready to be used for single use only. The ***Recovery Cone*** System is pre-assembled. Do not attempt to re-sterilize this product.

This product should be stored in a cool (room temperature), dry place.

M. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product, that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited, to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion, or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country.

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet.

In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

Recovery Cone® Removal System

Do Not Re-sterilize.

Recovery Cone® Removal System Introducer Catheter

Do Not Use If Package Is Damaged Or Opened.

REF

Catalog Number

Recommended Guidewire

Use By

Manufactured By

LOT

Lot Number

Contents: REF: FBRC Kit A: One (1) 10 Fr. Introducer Catheter 75cm Long with Dilator Kit B: One (1) Recovery Cone Removal System

Attention, See Instructions for Use

Bard, Recovery and Recovery Cone are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

STERILE EO

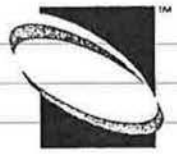
Sterilized By Using Ethylene Oxide

U.S. Patent No. 6,156,055. Other Patents Pending.
 Printed in the U.S.A.

NON PYROGENIC

Non-pyrogenic

Single Use. Do Not Reuse.



BARD

PERIPHERAL VASCULAR

Manufactured By:
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1-800-440-5376
www.bardpv.com

PK5014899 Rev. 0 11/07

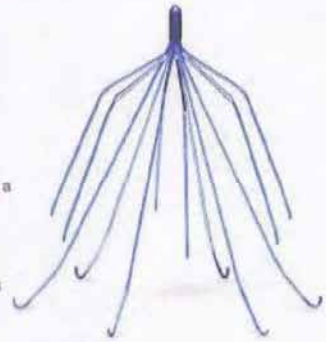
EXHIBIT CC

RECOVERY G2 FILTER SYSTEM

Timeless Performance†

NOW AVAILABLE - JUGULAR DELIVERY SYSTEM

The Recovery† G2 Filter combines **the best design features** of Bard's existing vena cava filters to create a **brand-new filter platform** — taking strength and stability to a new level.



The newly enhanced Recovery† G2 Filter continues the Bard tradition of filter innovation spanning over a decade.

- Increased **MIGRATION RESISTANCE***
- **IMPROVED CENTERING***
- Enhanced **FRACTURE RESISTANCE***

* Data on File

Clot Trapping and Caval Patency

The Recovery† G2 Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced Recovery† G2 Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm. Data on File

Low-Profile

7F delivery system is the lowest profile of any conical filter on the market.

Self-Centering

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

Recovery Cone® Removal System for use with the Recovery® Filter and Foreign Body Retrievals

ENGLISH

Instructions for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

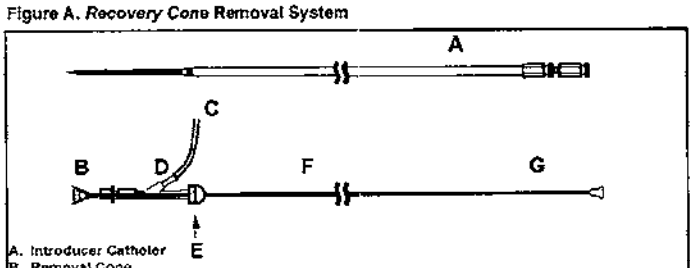
The ***Recovery Cone*** Removal System is intended to percutaneously remove the ***Recovery*** Filter or a foreign body as indicated.

The cone is designed to advance through its 75 cm, 10 French I.D. introducer catheter using a flexible, Pebax shaft. A reinforced cone at the end of the shaft is designed to collapse over the tip of the ***Recovery*** Filter or a foreign body for percutaneous removal. This cone is reinforced by a wire basket. The introducer sheath has a radiopaque marker for enhanced visualization. The introducer sheath is used to collapse the removal cone over the ***Recovery*** Filter tip or a foreign body and pull the collapsed cone into the sheath to remove the Filter or foreign body.

B. Device Description

The ***Recovery Cone*** Removal System consists of the ***Recovery Cone*** and Introducer Catheter (Figure A). The cone consists of a reinforced urethane cone, 15-mm in diameter. The cone is connected to a plastic (Pebax) shaft and handle. The shaft has a central lumen that accommodates a 0.035" guidewire. A Touhy-Borst Y-adapter is used to connect the cone to the Introducer Catheter and to a saline flush or drip. The Introducer Catheter consists of a 10 French I.D. introducer sheath and dilator. The introducer sheath has a radiopaque marker for enhanced fluoroscopic visualization.

Figure A. *Recovery Cone* Removal System



A. Introducer Catheter
B. Removal Cone
C. Saline Drip Infusion Set
D. Side Port
E. Adjustable Touhy-Borst Adapter
F. Shaft With 0.040" Lumen
G. Shaft Handle

IMPORTANT: Read instructions carefully before using the *Recovery Cone* Removal System

C. Indications for Use

The ***Recovery Cone*** Removal System is intended for use to percutaneously remove the ***Recovery*** Filter or facilitate the retrieval of foreign objects from the peripheral vascular system.

D. Contraindications for Use

None known.

E. Warnings

- Do not attempt to remove the ***Recovery*** Filter if significant amounts of thrombus are trapped within the Filter or if the Filter tip is embedded within the vena caval wall.
- Do not use excessive force when manipulating the cone. Excessive force may damage the catheter or other parts of the Recovery Cone.
- When attempting to retrieve a ***Recovery*** Filter, only use the ***Recovery Cone*** Removal System. Use of other devices has resulted in recurrent pulmonary embolism.
- Ensure adequate clearance in small vessels before deploying the ***Recovery Cone***.
- Withdrawal of large foreign bodies may require a cut-down at the peripheral site.
- If resistance is experienced during the retrieval procedure, check the captured Filter or foreign body and introducer sheath using fluoroscopy.
- Contents are supplied sterile. Do not use if sterile barrier is damaged. If damage is found, contact your Bard representative.
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- Do not use the device or accessories after the expiration date.

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- Spinal deformations: It is important to exercise care when contemplating removing the ***Recovery*** Filter or a foreign body from the inferior vena cava with the ***Recovery Cone*** Removal System in patients with significant kyphoscoliotic spinal deformations because the vessel may follow the general course of such anatomic deformations. This may require advanced techniques to remove the Filter or foreign body.
- After use, the ***Recovery Cone*** Removal System and its accessories and insertions supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.
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Possible complications of ***Recovery Cone*** usage include, but are not limited to, the following:

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- Hematoma at the access site
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- Sterile extension tube for saline drip or syringe for saline infusion
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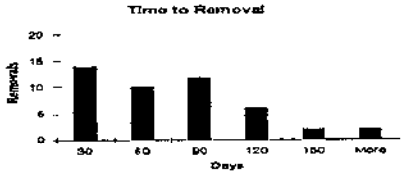
I. Clinical Experience with Recovery Filter

The ***Recovery*** Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 Filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with Filters in place of causes unrelated to Filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days (see histogram).



Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein jugular (n=1). One was removed surgically during a cancer operation where the mass was impinging on the Filter. The two methods described in the Instructions for Use were used to retrieve the Filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the ***Recovery Cone*** System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other adverse event reported was a fractured Filter arm and hook. This Filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The Filter was retrieved, minus the hook.

Clinical Experience Summary Table	
Recovery Filters Implanted	58
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	8-89 years (52 years average)
Reason for Filter Placement	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	3
Prophylaxis	2
Time to removal	1-161 days (60 days average)
Follow-up post-removal	1-901 days (325 average)
Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1
Asymptomatic pulmonary embolism post-removal	1

J. Directions for Use – *Recovery* Filter Removal
(See Section K for Foreign Body Retrieval Directions for Use)

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone***® Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the ***Recovery***® Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the Filter. If there is significant thrombus within the Filter, do not remove the ***Recovery*** Filter.

***Recovery Cone* Insertion and Delivery**

11. Remove the cone and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and Filter delivery system should be held in a straight line to minimize friction.
16. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
17. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the shaft and retracting the catheter.

Capture of *Recovery* Filter
***Recovery* Filter Removal**

18. The capture of the ***Recovery*** Filter is illustrated in ***Recovery*** Filter Removal - Figures A-E:

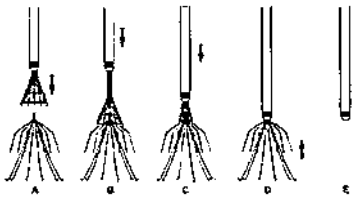


Figure A: After the cone has been opened superior to the Filter, advance the cone over the Filter by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the Filter tip.

Figure B: Close the cone over the Filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the Filter, remove the Filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The Filter has been retracted into the catheter.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed after withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***Recovery*** Filter, guidewire assisted techniques may be used.

Use of a Guidewire

If it is difficult to advance the ***Recovery Cone*** System over the ***Recovery*** Filter tip, one may use a guidewire to facilitate advancement of the cone.
Withdraw the introducer sheath and cone shaft away from the Filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the Filter near the Filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the Filter tip, advance the cone over the guidewire to the Filter tip.

Advance the introducer sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 18.

K. Directions for Use – Foreign Body Retrieval

1. Select a suitable entry site to access the foreign body.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform puncture with an 18 gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the foreign body.
6. Remove the entry needle over the guidewire.
7. Pre-dilate the insertion site with a 12F dilator and then advance the introducer catheter together with its tapered dilator over the guidewire to the target area.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

8. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently with saline to maintain introducer catheter patency.
9. Remove the cone and pusher system from Kit B.
10. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
11. Slowly withdraw the cone into the Y-adapter to collapse the cone

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

12. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
13. Attach the Y-adapter with the collapsed cone to the introducer catheter.
14. Advance the cone by moving the pusher shaft forward through the introducer catheter.
15. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter.
16. Open the cone by stabilizing the shaft and retracting the catheter
17. After the cone has been opened adjacent to the foreign body, advance the cone over foreign body by holding the introducer catheter stationary and advancing the pusher shaft.
18. Close the cone over the foreign body by advancing the introducer catheter over the cone while holding the pusher shaft stationary.
19. Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
20. With the cone collapsed over the foreign body, remove the foreign body by stabilizing the introducer catheter and retracting the pusher shaft in one smooth, continuous motion.

L. How Supplied

Each ***Recovery Cone*** Removal System is supplied preloaded. Each ***Recovery Cone*** Removal System is sterile and non-pyrogenic unless package has been opened or damaged, and is ready to be used for single use only. The ***Recovery Cone*** System is pre-assembled. Do not attempt to re-sterilize this product.

This product should be stored in a cool (room temperature), dry place.

M. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product, that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited, to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion, or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country.

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet.

In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

Recovery Cone® Removal System

Do Not Re-sterilize.

Recovery Cone® Removal System Introducer Catheter

Do Not Use If Package Is Damaged Or Opened.

REF

Catalog Number

Recommended Guidewire

Use By

Manufactured By

LOT

Lot Number

Contents: REF: FBRC Kit A: One (1) 10 Fr. Introducer Catheter 75cm Long with Dilator Kit B: One (1) Recovery Cone Removal System

Attention, See Instructions for Use

Bard, Recovery and Recovery Cone are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

STERILE EO

Sterilized By Using Ethylene Oxide

U.S. Patent No. 6,156,055. Other Patents Pending.

NON PYROGENIC

Non-pyrogenic

Single Use. Do Not Reuse.

BARD

PERIPHERAL VASCULAR

Manufactured By:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

TEL: 1-480-894-9515
1-800-321-4254
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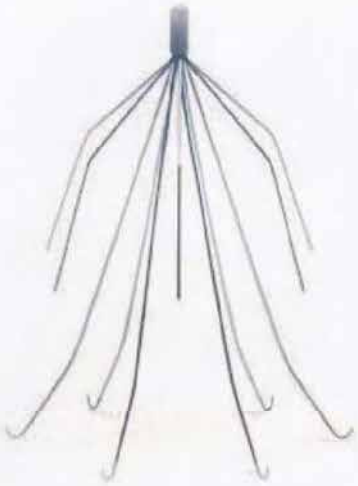
1-800-440-5375
www.bardpv.com

PK5014899 Rev. 0 11/07

RECOVERY Cone† Removal System

RECOVERY Timeless Performance†

RECOVERY® Filter's unique self-centering design, proven conical shape and bi-level filtering system create the ideal balance between clot trapping efficiency and caval patency. Advanced design and accurate placement coupled with lasting performance make RECOVERY® the permanent solution for caval interruption.



Low Profile

- At 7F, RECOVERY® Filter's delivery system has one of the lowest profiles of any filter on the market.

Clot Trapping and Caval Patency

- The RECOVERY® Filter utilizes the proven conical filter shape arranged into two offset layers to create a filtration system that effectively traps large and small emboli without compromising caval patency.

Self-Centering

- Articulated arms, along with the specially engineered flexible pusher wire of the delivery system, promote a centered placement.

Latest Advance in Filter Technology

- The RECOVERY® Filter, a product of Bard's industry-leading nitinol experience, incorporates the best features of today's most advanced caval filtration devices while overcoming the disadvantages with older designs.

Secure Fixation

- Filter hooks are loaded into a delivery system that is specifically constructed to prevent leg crossing.

G2 EXPRESS™
VENA CAVA FILTER

Manage the patient. Not the Filter.™

The outstanding performance of the G2 EXPRESS™ Filter combined with the long-term retrievability enables you to focus on MANAGING THE PATIENT – NOT THE FILTER.

EXERCISE YOUR OPTIONS

MULTIPLE RETRIEVAL OPTIONS FOR SAFE AND EASY RETRIEVAL

Endovascular Snare Retrieval

1. Position the snare over the hook.
2. Advance the snare catheter to close the snare. Then advance the sheath to the apex of the filter.
3. Retract the filter into the sheath.
4. Continue to pull the filter into the sheath.

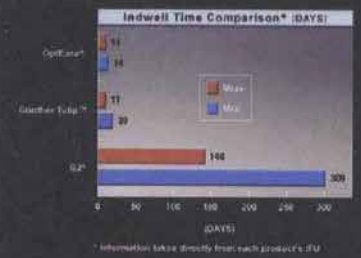
Use an Endovascular Snare or the Recovery Cone® Removal system to retrieve the G2 EXPRESS™ Filter — your preference.

Recovery Cone® Removal System Retrieval

1. Position the cone over the filter.
2. Advance the sheath to close the cone.
3. Retract the filter into the sheath.
4. Continue to pull the filter into the sheath.

LONGEST INDWELL TIME

Unique design of "elastic" hooks allow for atraumatic filter removal even after extended indwell times.



* Information taken directly from each product's IFU

SELF-CENTERING

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

ACCURATE DEPLOYMENT

Simple and familiar "pin-and-pull" deployment mechanism promotes accurate placement at the intended location.

EASY TO USE

Filter is completely loaded into the delivery system for easy assembly and delivery.

CLOT TRAPPING & CAVAL PATENCY

The G2 EXPRESS™ Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

G2® X
VENA CAVA FILTER

Manage the patient, Not the Filter™

The outstanding performance of the G2® X Filter combined with the long-term retrievability enables you to MANAGE THE PATIENT – NOT THE FILTER.™

EXERCISE YOUR OPTIONS

MULTIPLE RETRIEVAL OPTIONS FOR SAFE AND EASY RETRIEVAL

Endovascular Snare Retrieval

1. Position the snare over the hook.
2. Advance the snare catheter to close the snare. Then advance the sheath to the apex of the filter.
3. Retract the filter into the sheath.
4. Continue to pull the filter into the sheath.

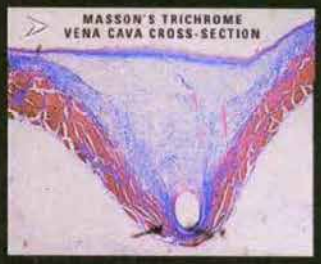
Use an Endovascular Snare or the Recovery Cone® Removal system to retrieve the G2® X Filter — your preference.

Recovery Cone® Removal System Retrieval

1. Position the cone over the filter.
2. Advance the sheath to close the cone.
3. Retract the filter into the sheath.
4. Continue to pull the filter into the sheath.

EXTENDED DWELL TIME

Unique design of "elastic" hooks allow for atraumatic filter removal even after extended indwell times. Actual Masson's Trichrome cross-section of the caval wall shows atraumatic removal of the filter. The white oval is the sleeve left behind after an "elastic" hook was removed.



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Vena Cava Filters

G2® X Filter System

Product Code	Description	Units/Box	Sheath Length
RF-400F	Femoral Delivery Kit	1	48 cm
RF-400J	Jugular/Subclavian Delivery System	1	55 cm
RF-4510F	Femoral Introducer Set	2	
RF-4520J	Jugular/Subclavian Introducer Set	2	

PULMONARY EMBOLISM AND VENA CAVA FILTERS

Your doctor has given you this booklet to help you learn more about pulmonary embolism – what causes it, how it can affect your body and, most important, how it can be treated. After reading the booklet, talk to your doctor about any questions you have. It's important to remember that each patient is different and that only your doctor can give you information about the details of your specific treatment.

WHAT IS PULMONARY EMBOLISM AND WHAT CAUSES IT?

Pulmonary embolism is the condition that results when a blood clot forms, usually in the deep veins of the lower leg, and becomes dislodged, traveling upward from the legs in the bloodstream. If left untreated, there is a possibility that the clot may move up into the arteries that carry blood to the lungs. If this occurs, the normal functioning of the lungs may be impaired.

WHAT TYPES OF TREATMENT ARE USED FOR PULMONARY EMBOLISM?

The most common treatment is a group of medications called anticoagulants or "blood thinners," however there are some patients who, for a variety of medical reasons, cannot take anticoagulants. For these individuals, a vena cava filter may offer an effective treatment solution.

WHAT IS A VENA CAVA FILTER?

A vena cava filter is an expandable metal device specially designed to trap blood clots before they reach the lungs. The filter is placed in the inferior vena cava (IVC) – the large vein that carries blood from the lower extremities back to the heart and lungs – and remains in place to trap clots before they move further up toward the lungs.

G2® X VENA CAVA FILTER

THE IMPLANT PROCEDURE

The anatomical sites identified below will provide general guidance on those areas that are important to an implant procedure.

HOW WILL THE FILTER BE INSERTED?

Your physician will insert the filter through either the right or left femoral or jugular vein (see anatomical illustration on opposite page). To make the procedure as easy as possible, the filter is inserted inside a small plastic tube called a catheter. Once inserted, the filter expands to its predetermined shape and is held in place against the vena cava walls.

HOW LONG DOES THE PROCEDURE USUALLY TAKE?

Although it varies depending upon the individual patient and the specific circumstances, the implantation of the filter generally takes less than an hour.

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

Local anesthesia, plus a mild sedative that might be taken before the procedure, will normally result in little to no discomfort while the filter is being implanted.

HOW LONG WILL IT TAKE TO FULLY RECOVER?

Recovery from the procedure should be rapid, although the specific length of time will vary from patient to patient depending upon factors such as age, general state of health, etc.

Have your physician fill out the back of this Patient Implant Card for you. Keep the card with you at all times.

RESUMING YOUR NORMAL LIFESTYLE

SHOULD I RESTRICT MY ACTIVITIES AFTER THE FILTER IMPLANTATION OR REMOVAL PROCEDURE?

The implantation or removal of a vena cava filter is not necessarily a reason to restrict your normal activity level. **However**, each patient is unique and there may be other medical reasons for doing so. Be sure to discuss with your doctor what level of activity is most appropriate for you following the procedure.

REMOVAL PROCEDURE

HOW WILL THE FILTER BE REMOVED?

Your physician will remove the filter through either the right or left internal jugular vein (see anatomic illustration on page 4). He/she will insert a small tube called a catheter. Through the catheter, a grasping device will be advanced to the filter. The filter will be grasped, and then pulled into the catheter. Your physician will then remove the entire system together.

HOW LONG DOES THE RETRIEVAL PROCEDURE TAKE?

Although it varies depending upon the individual patient and the specific circumstances, the retrieval of the filter generally takes less than an hour.

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

As with the implant procedure, local anesthesia helped by a mild sedative given before the procedure will normally result in little to no discomfort while the filter is being removed. Afterwards, you may experience mild soreness in your neck for a few days. This is normal and will disappear. You will be left with a small scar on your neck at the puncture site.

HOW LONG WILL IT TAKE TO FULLY RECOVER FROM THE REMOVAL PROCEDURE?

Recovery from the retrieval procedure should be rapid although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc. Typically you will be discharged several (2-3) hours after the procedure.

DOES THE FILTER HAVE TO BE REMOVED?

No. The G2® X Filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced.

AFTER THE PROCEDURE

HOW LONG WILL THE FILTER LAST?

The G2® X Filter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced.

CAN THE FILTER BECOME CLOGGED?

In the great majority of cases, the answer is "No." Once it has become entrapped in the filter, the normal flow of your blood through the vena cava and the filter will usually dissolve a trapped clot as the blood flows over it.

IF I SHOULD NEED AN MRI EXAM, WILL THE METAL FILTER INTERFERE WITH THE TEST?

The G2® X Filter is made from an alloy of nickel and titanium, and will not interfere with the test.

UNDER WHAT CIRCUMSTANCES SHOULD I CONTACT THE DOCTOR RIGHT AWAY?

You should contact your physician right away if you experience any of the following:

- sudden onset of chest pain accompanied by shortness of breath
- swelling in both legs
- unexplained pain in the abdomen

CAN THE FILTER BE REMOVED?

Yes. The filter can be removed when your physician determines that you no longer need it.

WHEN CAN THE FILTER BE REMOVED? IS THERE A "CUTOFF DATE" BY WHICH THE FILTER MUST BE REMOVED?

The G2® X Filter does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to your physician.

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Vena Cava Filters

G2® Filter System

Product Code	Description	Units/Box
RF-310F	Femoral Delivery Kit	1
RF-320J	Jugular/Subclavian Delivery Kit	1

G2® X

VENA CAVA FILTER

Jugular/Subclavian Vein Approach
Instructions for Use

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Instructions for Use
For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The ***GZ® X*** Filter is a venous interruption device designed to prevent pulmonary embolism. The unique design and material of the ***GZ® X*** Filter provide filtering efficiency and allow percutaneous placement through an angiographic introducer with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The ***GZ® X*** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The jugular/subclavian system allows for placement of the ***GZ® X*** Filter via a jugular or subclavian vein approach. The jugular/subclavian system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.038" guidewire and allows for an 800 psi maximum pressure contrast power injection. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the ***GZ® X*** Filter. The delivery device contains a spline cap that mechanically separates the filter anchors from one another in a unique pattern to prevent leg entanglement. The ***GZ® X*** Filter is preloaded within the delivery device. Once the introducer sheath is within position, the delivery device is advanced through the introducer sheath until the introducer and delivery hubs snap together. The safety clip is then removed. The introducer hub is pulled back over the pusher wire handle to unsheathe and release the ***GZ® X*** Filter allowing it to recover to its predetermined shape.

The ***GZ® X*** Filter is designed to act as a permanent filter. When clinically indicated, the ***GZ® X*** Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The ***GZ® X*** Filter's anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed (reference Optional Procedure for Filter Removal for specific removal instructions).

MRI Safety:

The ***GZ® X*** Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the ***GZ® X*** Filter is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:
-Static magnetic field of 3-Tesla or less
-Spatial gradient magnetic field of 720-Gauss/cm or less
-Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the ***GZ® X*** Filter produced a temperature rise of 0.8°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ***GZ® X*** Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

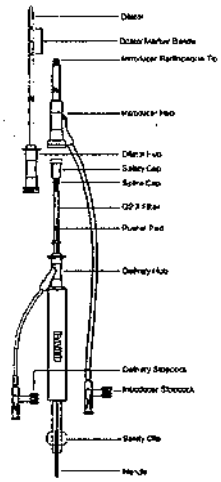
B. Device Description

The ***GZ® X*** Filter System - Jugular/Subclavian consists of the filter and delivery system. The ***GZ® X*** Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The ***GZ® X*** Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration.

The ***GZ® X*** Filter System - Jugular/Subclavian is illustrated in Figure 1. The Delivery System consists of a 10 French I.D. introducer sheath and dilator, the ***GZ® X*** Filter, and a delivery device. The ***GZ® X*** Filter is packaged pre-loaded within the delivery device.

Figure 1: *GZ® X* Filter System - Jugular/Subclavian



IMPORTANT: Read instructions carefully before using the *GZ® X* Filter

C. Indications for Use

The ***GZ® X*** Filter - Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
- ***GZ® X*** Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The ***GZ® X*** Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

D. Warnings

G2® X Filter Implantation

1. The *G2® X* Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2® X* Filter cannot be safely reloaded.
2. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4).
3. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.
4. Never re-deploy a removed filter.
5. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.
6. Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
7. Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
8. Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper *G2® X* Filter orientation within the IVC.
9. When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 300 psi.
10. Persons with allergic reactions to nickel may suffer an allergic response to this implant.
11. After use, the *G2® X* Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Reference Potential Complications section for further information regarding other known filter complications.

G2® X Filter Removal

1. Do not attempt to remove the G2® X Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

NOTE: It is possible that complications such as those described in the "Warnings," "Precautions," or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

2. Never re-deploy a removed filter.
3. Remove the *G2® X* Filter using an intravascular snare or the *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.

E. Precautions

G2® X Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the retrieval hook 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or intravascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the *G2® X* using an intravascular snare or a *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the *G2® X* Filter.
11. Do not remove the safety clip until the introducer and the delivery device hubs are snapped together.
12. Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the *G2® X* Filter.
13. It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.
14. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system.

G2® X Filter Removal

1. Anatomical variances may complicate the removal procedure. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the *G2® X* Filter with the *Recovery Cone®* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. When using the *Recovery Cone®* Removal System, the cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device.

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intima. tear.
- Stenosis at implant site.
- Failure of filter expansion/ incomplete expansion
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

- One G2® X Filter Jugular/Subclavian System that contains:
  - One 55 cm, 10 French I.D. introducer and dilator set
  - One delivery device with pre-loaded G2® X Filter
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18G entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

I. Directions for Use

1. Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient's size/anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape, and anesthetize the skin puncture site in standard fashion.
3. Select and open the carton and outer pouch. Open the introducer sheath and dilator inner pouch.
4. Nick the skin with a #11 blade and perform venipuncture with an 18G entry needle
5. Insert a J-tipped guidewire and gently advance it into the inferior vena cava.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the 18G entry needle over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs snap together. Advance the 10 French introducer sheath together with its tapered dilator over the guidewire and into the inferior vena cava.

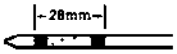
NOTE: A 0.038" guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

7. Remove the guidewire and perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

NOTE: IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).

Figure 2



WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 600 psi.

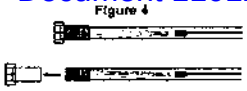
WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2® X Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath

8. Separate the dilator and introducer hubs by bending and then pulling apart (Reference Figure 3). Remove the guidewire and dilator, leaving the 10 French introducer sheath with its tip in the inferior vena cava. Flush intermittently by hand or attach to the introducer stopcock a constant saline drip infusion to maintain introducer patency.

Figure 3

9. Open the delivery system inner pouch. Remove the delivery device from the package and remove the red safety cap (Reference Figure 4).

Figure 4

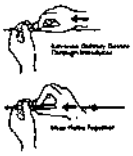


10. Flush the delivery device with saline through the delivery stopcock.
11. Insert and advance the delivery device through the introducer sheath until the introducer and delivery device hubs snap together (Reference Figure 5).

PRECAUTION: Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the GZ® X Filter.

NOTE: Do not remove the safety clip until step #13.

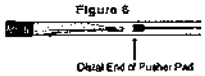
Figure 5



12. Under fluoroscopic control, position the system for optimal placement. The distal end of the pusher pad provides a radiopaque indicator for positioning purposes (Reference Figure 8).

NOTE: Do not remove the safety clip until step #13.

Figure 6

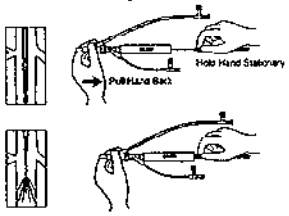


NOTE: A gap between the filter apex and pusher pad is normal.

13. Remove the safety clip from the delivery device.
14. Stabilize the handle and pull back on the introducer hub (blue) to retract both the introducer sheath and delivery device. Retract the introducer hub until the handle bottoms out against the proximal edge of the delivery catheter hub (white). This will release the GZ® X Filter into position (Reference Figure 7).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the GZ® X Filter.

Figure 7



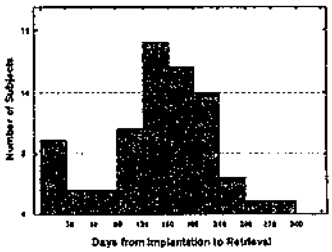
15. Separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.
16. Perform a venacavogram to confirm satisfactory deployment before terminating the procedure (typically 30mL of contrast medium at 15mL/s).
17. Remove the introducer sheath and apply routine compression over the puncture site in the usual manner to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the GZ® X Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 8 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anti-coagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis. The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 308 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 8 depicting the time to retrieval.

Figure 8: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the *Recovery Cone*® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Removal of GZ® X Filter Using an Intravascular Snare

Equipment Required

- One intravascular snare of user's choice
- One 80-cm introducer sheath, 7F ID or greater, to be used as retrieval sheath
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Procedural Instructions

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Remove the retrieval sheath from its packaging using sterile technique.
3. Prior to use, flush the retrieval sheath with heparinized saline or suitable isotonic solution.
4. Prepare all other procedure components according to the manufacturers' instructions for Use.
5. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
6. Select the appropriate loop diameter size of the intravascular snare.
7. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.
8. Insert the guidewire of choice into the retrieval sheath using the guidewire tip-straightener. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.
9. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.
10. Remove the guidewire.
11. Insert and advance the intravascular snare assembly through the sheath until it protrudes out of the sheath such that the marker band of the snare catheter is cephalad to the filter retrieval hook.
12. The retrieval of the **G2® X Filter** using an intravascular snare is illustrated **Figure 9 A-E.**

Figure 9 A-E: Retrieval of G2® X Filter using an Intravascular Snare, Illustrated

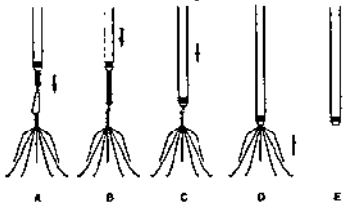


Figure 9 A: Slowly advance the loop forward over the filter apex.

Figure 9 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

NOTE: Ensure that the loop of the snare has properly engaged the retrieval hook and that the retrieval hook, retrieval catheter and snare are aligned. Be careful to snare the apex of the retrieval hook; not the side. The marker band of the snare catheter must be cephalad to the retrieval hook.

NOTE: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 9 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter

Figure 9 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 9 E: Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the G2® X Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena caval wall.

WARNING: Remove the G2® X Filter using an intravascular snare or the *Recovery Cone*® Removal System only.

13. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

14. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
15. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Removal of G2® X Filter Using the *Recovery Cone*® Removal System

Equipment Required

The following equipment is required for use:

- One ***Recovery Cone*® Removal System** that contains:
  - –One 75 cm, 10 French I.D. Introducer catheter and dilator set
  - –One Y-adapter with ***Recovery Cone*® Removal System** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture; scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to use the ***Recovery Cone*® Removal System** to remove the **G2® X Filter**, it is available from C. R. Bard, Inc.

***Procedural* Instructions**

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone*® Removal System** package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the **G2® X Filter** for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein, such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the **G2® X Filter.**

***Recovery Cone*® Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone*® Removal System** and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Loosen the Touhy-Borst and slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight line to minimize friction.

15. Advance the pusher shaft moving the distal tip forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.
17. The retrieval of the ***GZ® X*** Filter using a ***Recovery Cone®*** Removal System is illustrated in **Figure 10 A-E**:

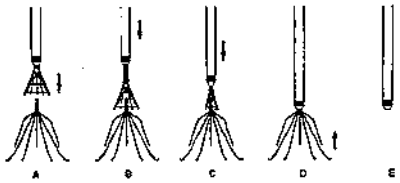


Figure 10 A-E: Retrieval of *GZ® X* Filter using *Recovery Cone®* Removal System, Illustrated

Figure 10 A: After the cone has been opened superior to the filter, carefully advance the cone over the retrieval hook by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the retrieval hook.

Figure 10 B: Close the cone over the retrieval hook by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure 10 C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure 10 D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion

Figure 10 E: The filter has been retracted into the catheter.

WARNING: Do not attempt to remove the *GZ® X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

WARNING: Remove the *GZ® X* Filter using an intravascular snare or the *Recovery Cone®* Removal System only.

NOTE: It is recommended to fluoroscopically image the filter in AP and lateral views during retrieval.

NOTE: If difficulty is encountered while attempting to engage the retrieval hook and/ or multiple passes are required, consider using an intravascular snare as an alternate retrieval method.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***GZ® X*** Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the ***GZ® X*** retrieval hook, a guidewire could be used to facilitate advancement of cone over the retrieval hook.

Withdraw the introducer catheter and cone shaft away from the retrieval hook. Insert a 0.035" 260cm guidewire through the central lumen (a stiff guidewire with J or angled tip is recommended). Advance the guidewire through the cone and through the filter near the retrieval hook.

After it has been confirmed that the guidewire is in contact with or in close proximity to the retrieval hook, advance the cone over the guidewire to the retrieval hook.

Advance the introducer catheter to slightly collapse the cone over the retrieval hook. Withdraw the guidewire into the pusher shaft. Continue removing the filter as described in step 17.

J. How Supplied

Each ***GZ® X*** Filter is supplied preloaded in a delivery device. Each ***GZ® X*** Filter is sterile and non-pyrogenic unless the package is damaged or opened, and is ready for single use only. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

WARNING: After use, the *GZ® X* Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The ***GZ® X*** Filter should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cave Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 36:673-684]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-64]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter After Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2005, 17(2), 299-302
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.

7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al., J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2008, 20(1), 157-165.

G2® X Filter

G2® X Filter Jugular/Subclavian Delivery Device

G2® X Filter Introducer Sheath With Dilator

JUG Jugular/Subclavian

Use By

LOT Lot Number

REF Catalog Number

Attention, See Instructions for Use

STERILE EO Sterilized By Using Ethylene Oxide

NON PYROGENIC Non-pyrogenic

Keep Dry

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use If Package Is Damaged Or Opened

MR MR Conditional

KIT (1) G2® X Filter Jugular/Subclavian Delivery Device (1) 10Fr. Introducer Sheath 55cm Long with Dilator

OD (1) G2® X Filter Jugular/Subclavian Delivery Device

SET (2) 10 Fr. Introducer Sheath 55cm Long with Dilator

Recommended Guidewire

Manufacturer

TM Bard, G2® X, and Recovery Cone® are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Variously Protected by one or more of the following U.S. Patent Numbers: 6,007,556 6,258,026 and 6,156,055. Other U.S. and foreign Patents Pending.

Manufacturer:
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BARD
PERIPHERAL
VASCULAR

PK5100070 Rev. 4 08/09

G2® X

VENA CAVA FILTER

Femoral Vein Approach
Instructions for Use

BARD
PERIPHERAL
VASCULAR

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The *GZ® X* Filter is a venous interruption device designed to prevent pulmonary embolism. The unique design and material of the *GZ® X* Filter provide filtering efficiency and allow percutaneous placement through a 7 French I.D. introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The *GZ® X* Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The Femoral system allows for placement of the *GZ® X* Filter via a femoral vein approach. The femoral delivery system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.035" guidewire and allows for an 800 psi maximum pressure contrast power injection. The 46cm, 7 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The flexible nitinol pusher wire of the delivery device has a pad at the end of the wire designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the radiopeque distal end of the introducer sheath, positioned 1 cm below the lowest renal vein. The introducer sheath and delivery device are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the *GZ® X* Filter to be deployed with the retrieval hook centered and minimizes the potential for legs crossing.

The *GZ® X* Filter is designed to act as a permanent filter. When clinically indicated, the *GZ® X* Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The *GZ® X* Filter's anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions).

MRI Safety:

The *GZ® X* Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the *GZ® X* Filter is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:
- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the *GZ® X* Filter produced a temperature rise of 0.6°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the *GZ® X* Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

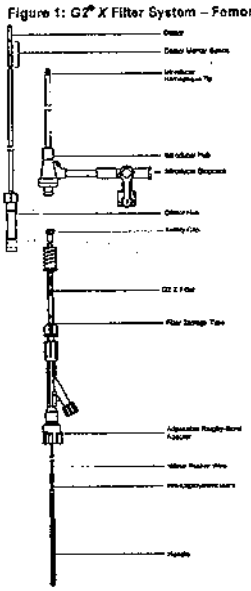
B. Device Description

The *GZ® X* Filter System - Femoral consists of the filter and delivery system. The *GZ® X* Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The *GZ® X* Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration.

The *GZ® X* Filter System - Femoral is illustrated in Figure 1. The delivery system consists of a 7 French I.D. introducer sheath and dilator, the *GZ® X* Filter, a storage tube with saline infusion port, and a pusher system. The *GZ® X* Filter is packaged pre-loaded within the delivery storage tube.

Figure 1: *GZ® X* Filter System – Femoral



IMPORTANT: Read instructions carefully before using the *GZ® X* Filter

C. Indications for Use

The *GZ® X* Filter - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:
- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- *GZ® X* Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The G2® X Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

***G2® X* Filter Implantation**

1. The ***G2® X*** **Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2® X* Filter cannot be safely reloaded into the storage tube.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to PRECAUTION # 4.)**
3. **Delivery of the *G2® X* Filter through the introducer sheath is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer sheath.**
4. **The *G2® X* Filter - Femoral is designed for femoral approaches only. Never use the *G2® X* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *G2® X* Filter orientation within the IVC.**
5. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.**
6. **Never re-deploy a removed filter.**
7. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 600 psi.**
8. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**
9. **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and /or surgical techniques.**
10. **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
11. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
12. **After use, the *G2® X* Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

***G2® X* Filter Removal**

1. **Do not attempt to remove the *G2® X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.**

NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of these Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

2. **Never re-deploy a removed filter.**
3. **Remove the *G2® X* Filter using an intravascular snare or the *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.**

F. PRECAUTIONS

***G2® X* Filter Implantation**

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the retrieval hook 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the *G2® X* Filter using an intravascular snare or a *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer sheath has a radiopaque distal tip to assist in visualization and predeployment filter positioning. The radiopaque distal tip on the introducer sheath, when used in conjunction with the radiopacity of the pusher wire spline, provides a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. Do not attempt to attach a syringe or power injection line to the proximal end of the introducer sheath hub.
12. Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.
13. It is very important to maintain introducer sheath patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
14. Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer sheath. Do not twist the pusher wire handle at anytime during this procedure.
15. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air to the system.

***G2® X* Filter Removal**

1. Anatomical variances may complicate the removal procedure. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the *G2® X* Filter in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. When using the *Recovery Cone®* Removal System, the cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device.

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary ConsensusConference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with possible complications that occur at any time during or after the procedure. Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion.
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain.
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One *GZ® X* Filter Femoral System that contains:
  - -One 48 cm, 7 French I.D. introducer sheath and dilator set
  - -One storage tube with pre-loaded *GZ® X* Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

I. Directions for Use

Insertion of the 7 French Introducer Sheath and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the carton and outer pouch. Open the introducer sheath and dilator inner pouch.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

PRECAUTION: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the 18G entry needle over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs connect properly. Advance the 7 French introducer sheath together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

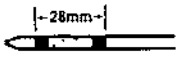
NOTE: A 0.038" guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

7. Remove the guidewire and perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

NOTE: IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).

Figure 2



WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 600 psi.

WARNING: If the vena cava diameter is greater than 28mm, do not deploy the *GZ® X* Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

8. Remove the dilator, leaving the introducer sheath with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer sheath a constant saline drip infusion to maintain introducer sheath patency.
9. Advance the introducer sheath to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer sheath tip should be 1 cm below the lowest renal vein.
10. Open the delivery system inner pouch. Remove the delivery system containing the filter from the package and remove the red safety cap (Reference Figure 3).

Figure 3: Safety Cap Removal

11. Flush the delivery system with saline through the Y-adapter.

PRECAUTION: It is very important to maintain introducer sheath patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer sheath already in the vein. The introducer sheath and filter delivery system should be held in a straight line to minimize friction.

PRECAUTION: Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

13. Loosen the Toughy-Borst and advance the filter by moving the nitinol pusher wire forward through the introducer sheath (Reference Figure 4 A-D). Do not pull back on the pusher wire, only advance the pusher wire forward.

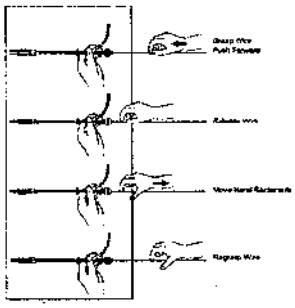
Figure 4 A-D: Advancement of Filter, Illustrated

FIGURE 4 A

FIGURE 4 B

FIGURE 4 C

FIGURE 4 D



14. Continue forward movement of the pusher wire until the filter retrieval hook advances to the radiopaque distal tip of the introducer sheath. At this point, the black mark on the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

15. Deliver and release filter as described in Figure 5 A-C:

Figure 5 A-C: Filter Release, Illustrated

FIGURE 5 A
FIGURE 5 A-1

FIGURE 5 B
FIGURE 5 B-1-

FIGURE 5 C
FIGURE 5 C-1

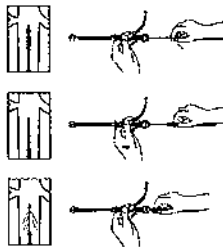


Figure 5 A: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure 5 A-1: Filter positioned at the distal end of the introducer sheath, with the filter retrieval hook, proximal to the introducer radiopaque tip.

PRECAUTION: Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer sheath as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter retrieval hook 1 cm below the lowest renal vein

Figure 5 B: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure 5 B-1: Unsheathing of filter in IVC.

Figure 5 C: The position of the hands at the completion of the unsheathing process.

Figure 5 C-1: The filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer sheath assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during the procedure.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer sheath patency.

Follow-up Venacavogram

18. A follow-up venacavogram may be performed after withdrawing the introducer sheath into the iliac vein (typically 30mL of contrast medium at 15mL/s).
19. Remove the introducer sheath and apply routine compression over the puncture site in the usual way to achieve hemostasis.

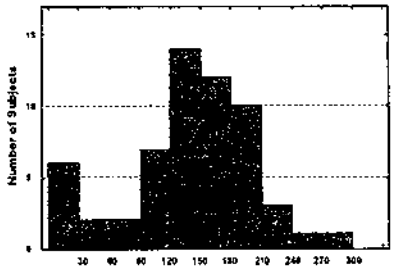
OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the *G2*® *X* Filter. 61 patients underwent a filter retrieval procedure in which 56 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6 . The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 56 patients with successful filter retrievals ranged from 5 to 309 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 6 depicting the time to retrieval.

Figure 6: Distribution of Filter Indwell Time in Retrieved Subjects



of the 67 attempted filter retrievals. Technical failure to retrieve resulted from inability to engage the filter apex with the *Recovery Cone*® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved. Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Removal of *GZ*® *X* Filter Using an Intravascular Snare

Equipment Required

- One intravascular snare of user's choice
- One 80-cm introducer sheath, 7F ID or greater, to be used as retrieval sheath
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Procedural Instructions

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Remove the retrieval sheath from its packaging using sterile technique.
3. Prior to use, flush the retrieval sheath with heparinized saline or suitable isotonic solution.
4. Prepare all other procedure components according to the manufacturers' Instructions for Use.
5. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
6. Select the appropriate loop diameter size of the intravascular snare.
7. Assemble the intravascular snare according to the instructions for use provided by its manufacturer.
8. Insert the guidewire of choice into the retrieval sheath using the guidewire tip-straightener. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.
9. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.
10. Remove the guidewire.
11. Insert and advance the intravascular snare assembly through the sheath until it protrudes out of the sheath such that the marker band of the snare catheter is cephalad to the filter retrieval hook.
12. The retrieval of the *GZ*® *X* Filter using an intravascular snare is illustrated in Figure 7 A-E:

Figure 7 A-E: Retrieval of *GZ*® *X* Filter using an Intravascular Snare, Illustrated

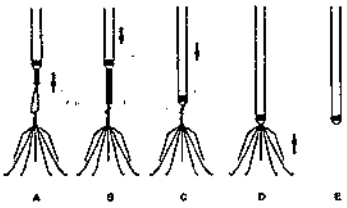


Figure 7 A: Slowly advance the loop forward over the filter apex.

Figure 7 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

NOTE: Ensure that the loop of the snare has properly engaged the retrieval hook and that the retrieval hook, retrieval catheter and snare are aligned. Be careful to snare the apex of the hook; not the side. The marker tip of the snare catheter must be cephalad to the filter retrieval hook.

NOTE: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 7 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter.

Figure 7 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 7 E: Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the *GZ*® *X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

WARNING: Remove the *GZ*® *X* Filter using an intravascular snare or the *Recovery Cone*® Removal System only.

13. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

14. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
15. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Removal of *GZ*® *X* Filter Using *Recovery Cone*® Removal System

Equipment Required

- One *Recovery Cone*® Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with *Recovery Cone*® Removal System and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to use the *Recovery Cone*® Removal System to remove the *GZ*® *X* Filter, it is available from C. R. Bard, Inc.

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the *Recovery Cone*® Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the *GZ*® *X* Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein, such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the *GZ*® *X* Filter.

***Recovery Cone*® Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone*®** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline-preferably heparinized saline.
13. Loosen the Touhy-Borst and slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.
17. The retrieval of the ***G2*® *X* Filter** using a ***Recovery Cone*®** Removal System is illustrated in Figure 8 A-E:

Figure 8 A-E: Retrieval of *G2*® *X* Filter using *Recovery Cone*® Removal System, Illustrated

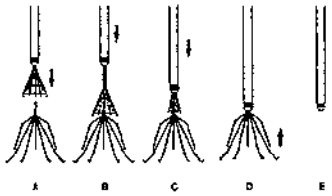


Figure 8 A: After the cone has been opened superior to the filter, carefully advance the cone over the retrieval hook by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the retrieval hook.
Figure 8 B: Close the cone over the retrieval hook by advancing the introducer catheter over the cone while holding the pusher shaft stationary.
Figure 8 C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
Figure 8 D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.
Figure 8 E: The filter has been retracted into the catheter.

WARNING: Do not attempt to remove the *G2*® *X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

WARNING: Remove the *G2*® *X* Filter using an intravascular snare or the *Recovery Cone*® Removal System only.

NOTE: It is recommended to fluoroscopically image the filter in AP and lateral views during retrieval.

NOTE: If difficulty is encountered while attempting to engage the retrieval hook and/ or multiple passes are required, consider using an intravascular snare as an alternate retrieval method.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***G2*® *X* Filter** guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the ***G2*® *X* Filter** retrieval hook, one may use a guidewire to facilitate advancement of cone over the retrieval hook.
Withdraw the introducer catheter and cone shaft away from the retrieval hook. Insert a 0.035" 260 cm guidewire through the central lumen (a stiff guidewire with J or angled tip is recommended).
Advance the guidewire through the cone and through the filter near the retrieval hook.
After it has been confirmed that the guidewire is in contact with or in close proximity to the retrieval hook, advance the cone over the guidewire to the retrieval hook.
Advance the introducer catheter to slightly collapse the cone over the retrieval hook. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each ***G2*® *X* Filter** is supplied preloaded in a storage tube. Each ***G2*® *X* Filter** is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

WARNING: After use, the *G2*® *X* Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The ***G2*® *X* filter** should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grass, Swan, Cardella, et al.; J Vasc Interv Radiol 2003; 14:S271-S275.

2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.; Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter After Dwell Times Longer than 180 Days. Binkert, C., et al.; J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.; J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hegspel, K., et al.; J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.; Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.; J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.; Annals of Vascular Surgery 2006, 20(1), 157-165.

G2® X Filter

G2® X Filter Femoral Delivery Device

G2® X Filter Introducer Sheath With Dilator

FEM Femoral

Use By

LOT Lot Number

REF Catalog Number

Attention, See Instructions for Use

STERILE EO Sterilized By Using Ethylene Oxide

NON PYROGENIC Non-pyrogenic

Keep Dry

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use If Package Is Damaged Or Opened

MR MR Conditional

KIT (1) 7 Fr. Introducer Sheath 45cm Long with Dilator

KIT (1) G2® X Filter - Femoral Delivery Device
(1) 7 Fr. Introducer Sheath 45cm Long with Dilator

DD (1) G2® X Filter - Femoral Delivery Device

SET (2) 7 Fr. Introducer Sheath 45cm Long with Dilator

L R Recommended Guidewire

Manufacturer:

TM Bard, G2® X and Recovery Cone® are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Variously Protected by one or more of the following U.S. Patent Numbers: 6,007,558 6,258,026 and 6,156,055. Other U.S. and foreign Patents Pending.

Manufacturer:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

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U.S. Vascular

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G2® Filter System

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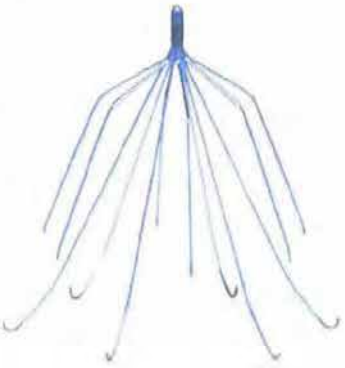
United States
Puerto Rico
US Virgin Islands

G2® FILTER SYSTEM

INDICATED FOR RETRIEVAL

The G2® Filter quickly established its exceptional performance as a permanent vena cava filter with over 65,000 units sold worldwide.



NOW WITH THE OPTION OF EXTENDED RETRIEVAL, the G2® Filter gives physicians **complete control** over their patients' care.

- Increased **MIGRATION RESISTANCE***
- **IMPROVED CENTERING***
- Enhanced **FRACTURE RESISTANCE***

* Data on File

Clot Trapping and Caval Patency

G2® Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2® Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm. Data on File.

Easy to Use

Filter is completely loaded into the delivery system for easy assembly and delivery.

Self-Centering

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

G2™ Filter System

G2 FILTER SYSTEM
for Permanent Placement

Timeless Performance

NOW AVAILABLE - JUGULAR DELIVERY SYSTEM

The G2™ Filter combines **the best design features** of Bard's existing vena cava filters to create a **brand-new permanent filter platform** — taking strength and stability to a new level.

The newly enhanced G2™ Filter continues the Bard tradition of filter innovation spanning over a decade.

- Increased **MIGRATION RESISTANCE***
- **IMPROVED CENTERING***
- Enhanced **FRACTURE RESISTANCE***

* Data on File

Clot Trapping and Caval Patency

G2™ Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2™ Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm. Data on File

Low-Profile

7F delivery system is the lowest profile of any conical filter on the market.

Self-Centering

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

BARD Peripheral Vascular — Product Catalog

United States
Puerto Rico
US Virgin Islands

Ordering Information – 800-321-4254

Return to Product Catalog

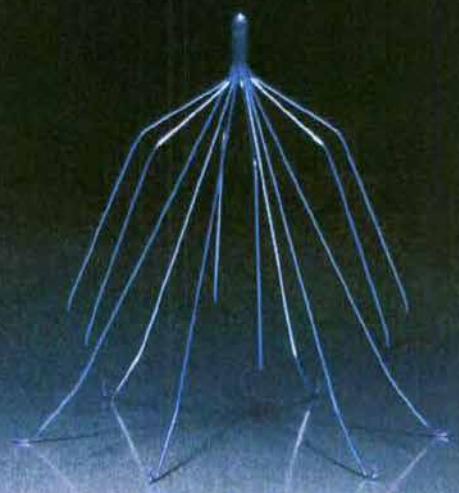
Vena Cava Filters

G2® Filter System

Product Code	Description	Units/Box
RF-310F	Femoral Delivery Kit	1
RF-320J	Jugular/Subclavian Delivery Kit	1

NOW INDICATED FOR RETRIEVAL

G2® FILTER SYSTEM



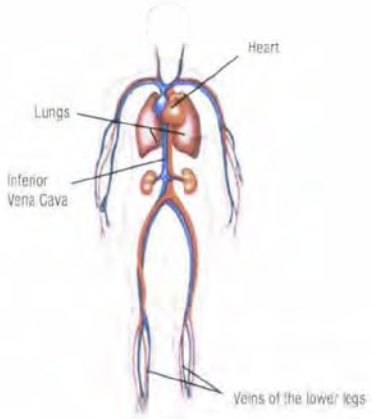
Vena Cava Filter

PATIENT QUESTIONS & ANSWERS

BARD PERIPHERAL VASCULAR

PULMONARY EMBOLISM AND VENA CAVA FILTERS

Your doctor has given you this booklet to help you learn more about pulmonary embolism – what causes it, how it can affect your body and, most important, how it can be treated. After reading the booklet, talk to your doctor about any questions you have. It's important to remember that each patient is different and that only your doctor can give you information about the details of your specific treatment.



WHAT IS PULMONARY EMBOLISM AND WHAT CAUSES IT?

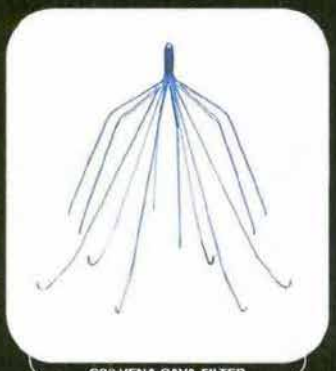
Pulmonary embolism is the condition that results when a blood clot forms, usually in the deep veins of the lower leg, and becomes loosened, traveling upward from the legs in the bloodstream. If left untreated, there is a possibility that the clot may move up into the arteries that carry blood to the lungs. If this occurs, the normal functioning of the lungs may be impaired.

WHAT TYPES OF TREATMENT ARE USED FOR PULMONARY EMBOLISM?

The most common treatment is a group of medications called anticoagulants or "blood thinners." However, there are some patients who, for a variety of medical reasons, cannot take anticoagulants. For these individuals, a vena cava filter may offer an effective treatment solution.

WHAT IS A VENA CAVA FILTER?

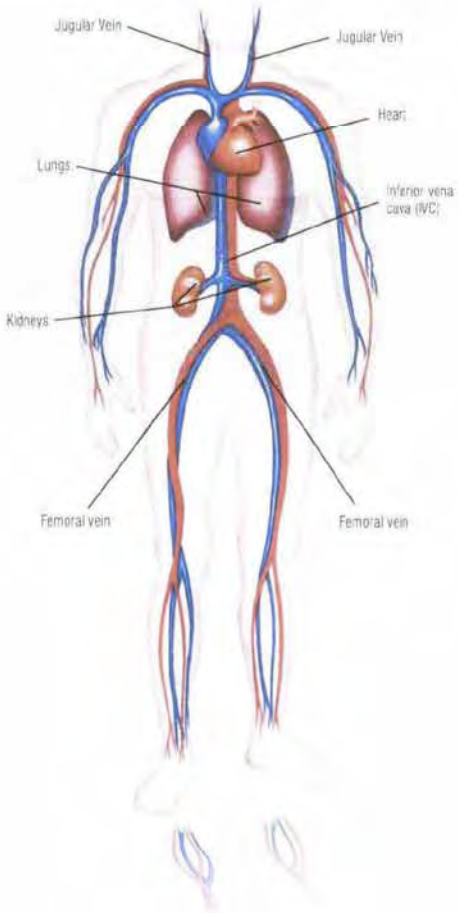
A vena cava filter is an expandable metal device specially designed to trap blood clots before they reach the lungs. The filter is placed in the inferior vena cava (IVC) – the large vein that carries blood from the lower extremities back to the heart and lungs – and remains in place to trap clots before they move further up toward the lungs.



G2® VENA CAVA FILTER

THE IMPLANT PROCEDURE

The anatomical sites identified below will provide general guidance on those areas that are important in an implant procedure.



HOW WILL THE FILTER BE INSERTED?

Your physician will insert the filter through either the right or left femoral vein in the upper thigh (see anatomical illustration on opposite page). To make the procedure as easy as possible, the filter is inserted inside a small plastic tube called a catheter. Once inserted, the filter expands to its predetermined shape and is held in place against the vena cava walls.

HOW LONG DOES THE PROCEDURE USUALLY TAKE?

Although it varies depending upon the individual patient and the specific circumstances, the implantation of the filter generally takes less than an hour.

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

Local anesthesia, plus a mild sedative that might be taken before the procedure, will normally result in little to no discomfort while the filter is being implanted.

HOW LONG WILL IT TAKE TO FULLY RECOVER?

Recovery from the procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc.

AFTER THE PROCEDURE

HOW LONG WILL THE FILTER LAST?

The G2® Filter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced.

CAN THE FILTER BECOME CLOGGED?

In the great majority of cases, the answer is "no." Once a clot becomes entrapped in the filter, the normal flow of your blood through the vena cava and the filter will usually dissolve a trapped clot as the blood flows over it.

IF I SHOULD NEED AN MRI EXAM, WILL THE METAL FILTER INTERFERE WITH THE TEST?

The G2® Filter is made from an alloy of nickel and titanium, and will not interfere with the test.

UNDER WHAT CIRCUMSTANCES SHOULD I CONTACT THE DOCTOR RIGHT AWAY?

You should contact your physician right away if you experience any of the following:

- sudden onset of chest pain accompanied by shortness of breath
- swelling in both legs
- unexplained pain in the abdomen

CAN THE FILTER BE REMOVED?

Yes. The filter can be removed when your physician determines that you no longer need it.

WHEN CAN THE FILTER BE REMOVED? IS THERE A "CUTOFF DATE" BY WHICH THE FILTER MUST BE REMOVED?

The G2® Filter does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to your physician.

REMOVAL PROCEDURE

HOW WILL THE FILTER BE REMOVED?

Your physician will remove the filter through either the right or left internal jugular vein (see anatomic illustration on page 4). He/she will insert a small tube called a catheter. Through the catheter, a grasping device will be advanced to the filter. The filter will be grasped, and then pulled into the catheter. Your physician will then remove the entire system together.

HOW LONG DOES THE RETRIEVAL PROCEDURE TAKE?

Although it varies depending upon the individual patient and the specific circumstances, the retrieval of the filter generally takes less than an hour.

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

As with the implant procedure, local anesthesia, helped by a mild sedative given before the procedure, will normally result in little to no discomfort while the filter is being removed. Afterwards, you may experience mild soreness in your neck for a few days. This is normal and will disappear. You will be left with a small scar on your neck at the puncture site.

HOW LONG WILL IT TAKE TO FULLY RECOVER FROM THE REMOVAL PROCEDURE?

Recovery from the removal procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc. Typically, you will be discharged several (2-3) hours after the procedure.

DOES THE FILTER HAVE TO BE REMOVED?

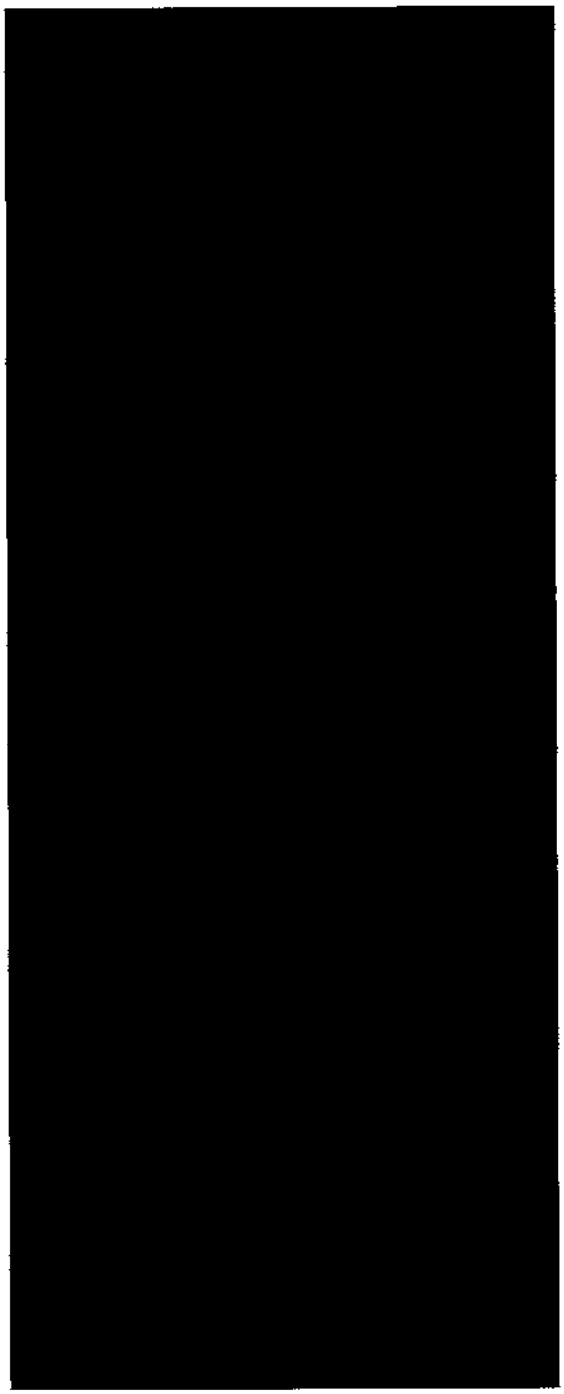
No. The G2^{x} Filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced.

RESUMING YOUR NORMAL LIFESTYLE

SHOULD I RESTRICT MY ACTIVITIES AFTER THE FILTER IMPLANTATION OR REMOVAL PROCEDURE?

The implantation or removal of a vena cava filter is not necessarily a reason to restrict your normal activity level; **however**, each patient is unique and there may be other medical reasons for doing so. Be sure to discuss with your doctor what level of activity is most appropriate for you following the procedure.

NOTES:



PATIENT
IMPLANT CARD

Patient Name _____

Date of Implant _____

Implant Site _____

Implanting Physician _____

Telephone No. _____

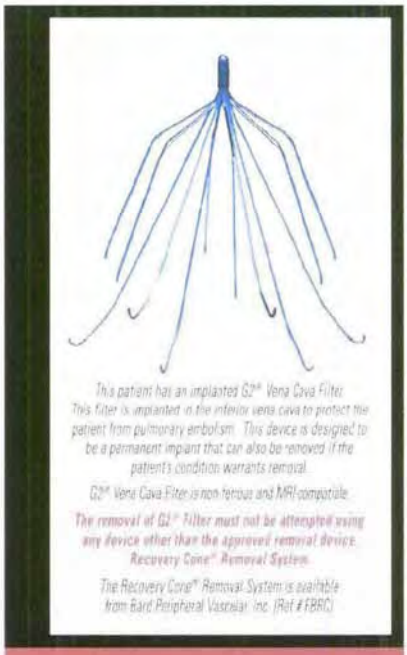
Implanting Hospital _____

City _____ State _____

BARD
PERIPHERAL
VASCULAR

Bard Peripheral Vascular, Inc.
1625 W. 3rd Street
Tempe, AZ 85281
USA
www.bardpv.com
Tel: 1.480.894.9515
1.800.321.4254
Fax: 1.480.966.7062
1.800.440.5376

Have your physician fill out this Patient Implant Card for you. Then, tear off at perforation and keep the card with you at all times.

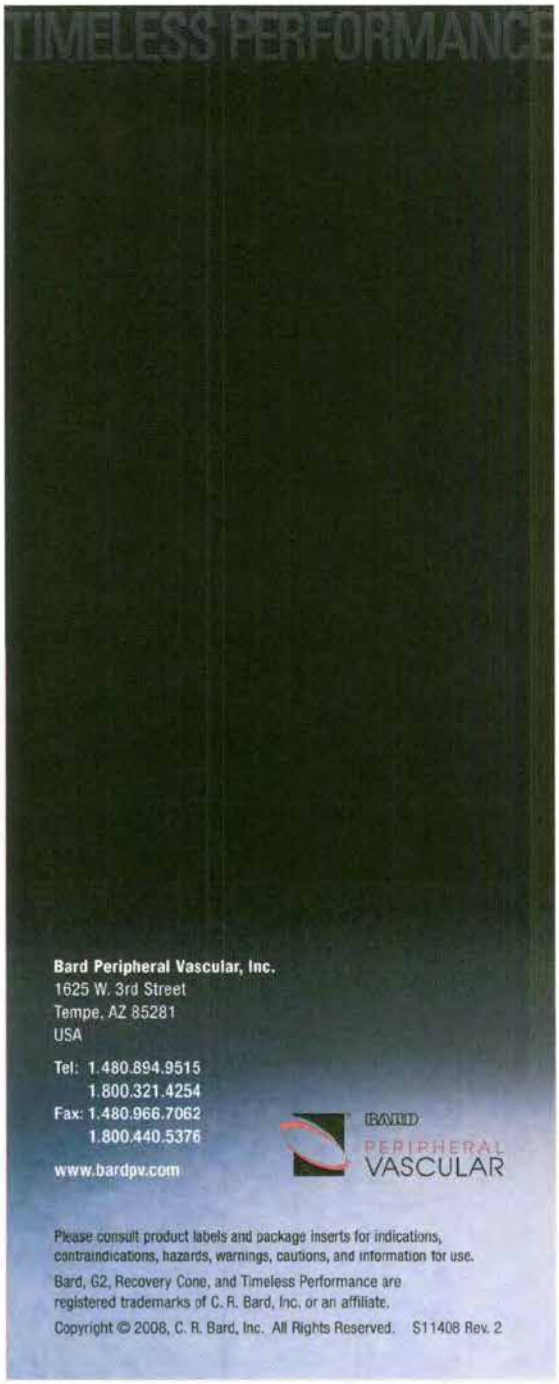


This patient has an implanted G2® Vena Cava Filter. This filter is implanted in the inferior vena cava to protect the patient from pulmonary embolism. This device is designed to be a permanent implant that can also be removed if the patient's condition warrants removal.

G2® Vena Cava Filter is non-ferrous and MRI compatible.

The removal of G2® Filter must not be attempted using any device other than the approved removal device, Recovery Cone® Removal System.

The Recovery Cone® Removal System is available from Bard Peripheral Vascular, Inc. (Ref # FBRC).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1.800.440.5376
www.bardpv.com
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G2® Filter System
Timeless Performance®

G2® Filter System
Jugular/Subclavian Vein Approach
Instructions for Use

BARD PERIPHERAL VASCULAR

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The G2® Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the G2® Filter provide filtering efficiency and allow percutaneous placement through an angiographic introducer with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The G2® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The Jugular/Subclavian system allows for placement of the G2® Filter via a jugular or subclavian vein approach. The jugular/subclavian system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.035" guidewire and allows for an 800 psi maximum pressure contrast power injection. The 16 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the G2® Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to prevent leg entanglement. The G2® Filter is preloaded within the delivery device. Once the introducer sheath is within position, the delivery device is advanced through the introducer sheath until the introducer and delivery hubs snap together. The safety clip is then removed. The introducer tab is pulled back over the pusher wire handle to unsheathe and release the G2® Filter allowing it to recover to its predetermined shape.

The G2® Filter is designed to act as a permanent filter. When clinically indicated, the G2® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2® Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.).

MRI Safety:

Non-clinical testing has demonstrated that the G2® Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less.
2. Spatial gradient field of 450 Gauss/cm or less.
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the G2® Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric HealthCare MR scanner.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2® Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

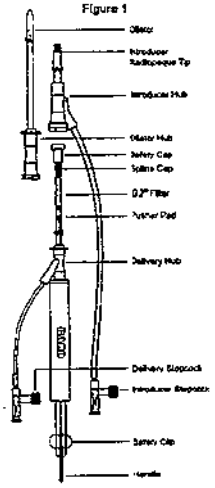
B. Device Description

The G2® Filter- Jugular/Subclavian System consists of the filter and delivery system. The G2® Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The G2® Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration.

The G2® Filter System -Jugular/Subclavian is illustrated in Figure 1. The Delivery System consists of a 16 French I.D. introducer sheath and dilator, the G2® Filter, and a delivery device. The G2® Filter is packaged pre-loaded within the delivery device.

Figure 1



IMPORTANT: Read instructions carefully before using the G2® Filter.

C. Indications for Use

The G2® Filter System- Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2® Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The G2® Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2® Filter Implantation

1. The G2® Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2® Filter cannot be safely reloaded.
2. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4).
3. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.
4. Only use the *Recovery Cone*® Removal System to remove the G2® Filter. Never re-deploy a removed filter.
5. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.
6. Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
7. Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
8. Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2® Filter orientation within the IVC.
9. When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.

10. Persons with allergic reactions to nickel may suffer an allergic response to this implant.
11. After the G2® Filter system and accessory components are opened, handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Reference Potential Complications section for further information regarding other known filter complications.

G2® Filter Removal

1. Do not attempt to remove the G2® Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall.
   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. Use only the Bard *Recovery Cone®* Removal System (packaged separately) to retrieve the G2® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.
3. Never re-deploy a removed filter.

F. Precautions

G2® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology
6. If malplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the G2® Filter using the *Recovery Cone®* Removal System Only. Refer to Optional Procedure for Filter Removal for details
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult
8. In persons with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe
9. If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the G2® filter.
11. Do not remove the safety clip until the introducer and the delivery device hubs are snapped together.
12. Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the G2® filter.
13. It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.
14. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system

G2® Filter Removal

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone®* Removal System. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the G2® Filter with the *Recovery Cone®* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the G2® Filter using the *Recovery Cone®* Removal System Only. Refer to the Optional Procedure for Filter Removal section for details.
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2003; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Reduction of blood flow.
- Occlusion of small vessels.
- Distal embolization
- Infection.
- Intimal tear.
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention, patient death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

- One G2® Filter Jugular/Subclavian System that contains:
  - -One 55 cm, 10 French I.D. introducer and dilator set
  - -One delivery device with pre-loaded G2® Filter
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18G entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to percutaneously remove the G2® Filter, the *Recovery Cone*® Removal System is available from C. R. Bard, Inc.

I. Directions for Use

1. Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient's size/anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape, and anesthetize the skin puncture site in standard fashion.
3. Select and open the jugular/subclavian delivery system package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18G entry needle.
5. Insert a J-tipped guidewire and gently advance it into the inferior vena cava.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the 18G entry needle over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs snap together. Advance the 10 French introducer sheath together with its tapered dilator over the guidewire and into the inferior vena cava.

NOTE: A 0.038" guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

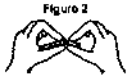
7. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 300 psi.

WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2® Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

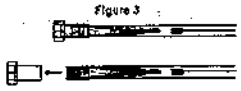
8. Separate the dilator and introducer hubs by bending and then pulling apart (Reference Figure 2). Remove the guidewire and dilator, leaving the 10 French introducer sheath with its tip in the inferior vena cava. Flush intermittently by hand or attach to the introducer stopcock a constant saline drip infusion to maintain introducer patency.

Figure 2



9. Remove the delivery device from the package and remove the red safety cap (Reference Figure 3).

Figure 3

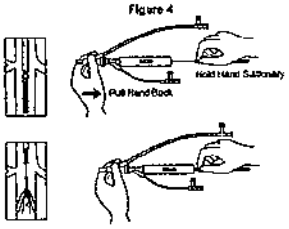


10. Flush the delivery device with saline through the delivery stopcock.
11. Insert and advance the delivery device through the introducer sheath until the introducer and delivery device hubs snap together (Reference Figure 4).

PRECAUTION: Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the G2® filter.

NOTE: Do not remove the safety clip until step #13.

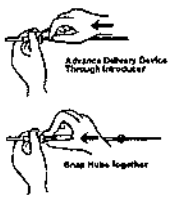
Figure 4



12. Under fluoroscopic control, position the system for optimal placement. The distal end of the pusher pad provides the radiopaque indicator for positioning purposes (Reference Figure 5).

NOTE: Do not remove the safety clip until step #13.

Figure 5

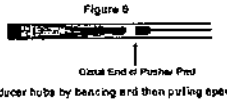


NOTE: A gap between the filter apex and pusher pad is normal.

13. Remove the safety clip from the delivery device.
14. Stabilize the handle and pull back on the introducer hub (blue) to retract both the introducer sheath and delivery device. Retract the introducer hub until the handle bottoms out against the proximal edge of the delivery catheter hub (white). This will release the G2® filter into position (Reference Figure 6).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the G2® filter.

Figure 6



15. Separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.
16. Perform a venacavogram to confirm satisfactory deployment before terminating the procedure.
17. Remove the introducer sheath and apply routine compression over the puncture site in the usual manner to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2® Filter using the *Recovery Cone*® Removal System only.

Removal of G2® Filter

Equipment Required

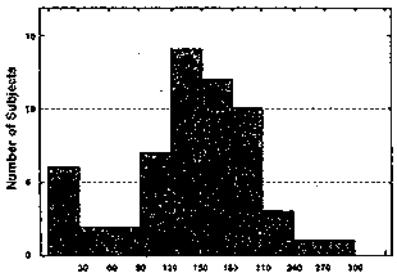
The following equipment is required for use:

- One *Recovery Cone*® Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with *Recovery Cone*® and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture; scalpel, #11 blade, local anesthetic, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the G2® Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement). The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis. The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 7 depicting the time to retrieval.

Figure 7: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the *Recovery Cone*® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=16), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the *Recovery Cone*® Removal System package. Open Kit A introducer catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the G2® Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the G2® Filter.

***Recovery Cone*® Removal System Insertion and Delivery**

11. Remove the *Recovery Cone*® Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

Filter Removal, Illustrated

17. The capture of the G2® Filter is illustrated in Figures A-E.

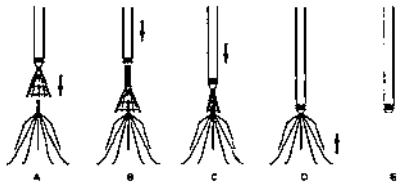


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an antero-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the G2® Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the G2® Filter tip, a guidewire could be used to facilitate advancement of the cone over the filter tip. Withdraw the introducer catheter and pusher shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip. After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the filter tip. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each *G2®* Filter is supplied preloaded in a delivery device. Each *G2®* Filter system is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

WARNING: After use, the G2® Filter system and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The *G2®* Filter system should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- "Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007: 38:673-684]
- "American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]
- "Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]
- "Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]

References:

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G2® Filter


G2® Filter System Jugular/Subclavian Delivery Device


G2® Filter System Introducer Sheath With Dilator


Jugular/Subclavian


Use By


Lot Number

Catalog Number


Attention, See Instructions for Use


Sterilized By Using Ethylene Oxide


Non-pyrogenic


Keep Dry


Protect From Heat


Single Use


Do Not Resterilize


Do Not Use If Package Is Damaged Or Opened.


MR Conditional


Contents:
G2® Filter Jugular/Subclavian Delivery Device
10 Fr. Introducer Sheath 55cm Long with Dilator


Recommended Guidewire


Manufacturer


Bard, G2®, Recovery Cone® and Timeless Performance are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.


Variously Protected by one or more of the following U.S. Patent Numbers: 8,007,558 and 6,258,026. Other U.S. and foreign Patents Pending.

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BARD
PERIPHERAL
VASCULAR

PK5260600 Rev. 1 07/09

G2® Filter System

Timeless Performance

G2® Filter System

Femoral Vein Approach

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The *G2®* Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the *G2®* Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the *G2®* Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The *G2®* Filter is designed to act as a permanent filter. When clinically indicated, the *G2®* Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The *G2®* Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the *G2®* Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic Field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the *G2®* Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

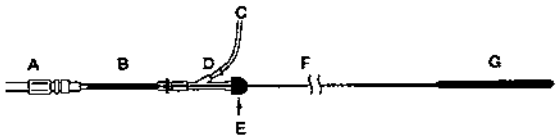
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the *G2®* Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

B. Device Description

The *G2®* Filter System - Femoral consists of the filter and delivery system. The *G2®* Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli. The legs provide the lower level of filtration and the arms provide the upper level of filtration. The *G2®* Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The *G2®* Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the *G2®* Filter, a storage tube with saline infusion port, and a pusher system. The *G2®* Filter is packaged pre-loaded within the delivery storage tube.

Figure A. *G2®* Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the *G2®* Filter

C. Indications for Use

The *G2®* Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- *G2®* Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

D. Contraindications for Use

The *G2®* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2® Filter Implantation

1. **The *G2®* Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2®* Filter cannot be safely reloaded into the storage tube.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)**
3. **Delivery of the *G2®* Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.**
4. **The *G2®* Filter System - Femoral is designed for femoral approaches only. Never use the *G2®* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *G2®* Filter orientation within the IVC.**
5. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.**
6. **Only use the *Recovery Cone®* Removal System to remove the *G2®* Filter. Never re-deploy a removed filter.**
7. **Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.**
8. **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
9. **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
10. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
11. **After use, the *G2®* Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

G2® Filter Removal

1. **Do not attempt to remove the *G2®* Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena cava wall.**

   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. **Use only the Bard *Recovery Cone®* Removal System (packaged separately) to retrieve the *G2®* Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.**
3. **Never re-deploy a removed filter.**

F. Precautions

G2® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the *G2®* Filter using a *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
12. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
13. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

G2® Filter Removal

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone®* Removal System. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the *G2®* Filter with the *Recovery Cone®* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the *G2®* Filter using the *Recovery® Cone* Removal System Only. (Reference Optional Procedure for Filter Removal for specific removal instructions).
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One G2® filter and Delivery System that contains:
  - One 45cm, 7 French I.D. introducer catheter and dilator set
  - One Storage tube with pre-loaded G2® Filter and pusher delivery system
- 0.035" 3mm J-tipped Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: Scalpel, #11 blade, local anesthesia, drapes, etc

If the physician chooses to percutaneously remove the G2® Filter, the ***Recovery Cone®*** Removal System is available from C.R. Bard, Inc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

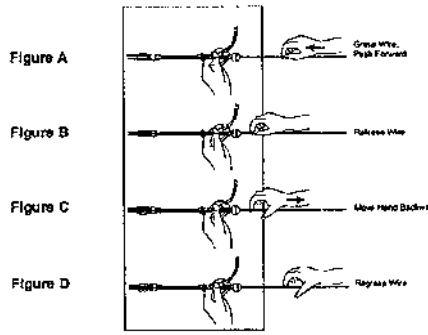
Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

Advancement of G2® Filter, Illustrated



13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

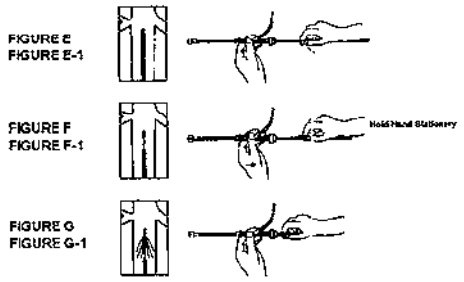
Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tub assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2® Filter using the *Recovery Cone®* only.

Removal of G2® Filter

Equipment Required

The following equipment is required for use:

- One ***Recovery Cone®*** Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with ***Recovery Cone®*** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium

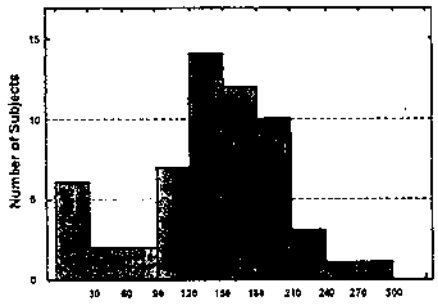
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the *G2®* Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time to retrieval.

Figure H: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the *Recovery Cone®* Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the *Recovery Cone®* Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the **G2®** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the **G2®** Filter.

***Recovery Cone®* Removal System Insertion and Delivery**

11. Remove the *Recovery Cone®* Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-acepter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

17. The capture of the **G2®** Filter is illustrated in **Figures A-E**:

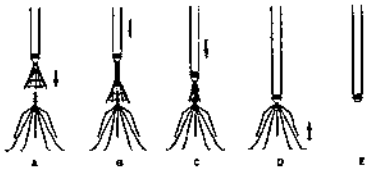


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the **G2®** Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the **G2®** Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip, a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17

J. How Supplied

Each *G2®* Filter is supplied preloaded in a storage tube. Each **G2®** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Warning: After use, the *G2®* Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The *G2®* Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 498-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hegspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.

G2® Filter System

Femoral

Femoral Introducer Catheter

Use By

Lot Number

Catalog Number

Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Non-pyrogenic

Single Use.

Do Not Resterilize.

Do Not Use If Package Is Damaged Or Opened.

MR Conditional

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System

Protect From Heat

Keep Dry

Recommended Guidewire

Manufacturer:

Bard, G2®, Recovery Cone® and Timeless Performance are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Variously protected by one or more of the following U.S. Patents: 8,007,658 and 6,258,026. Other U.S. and Foreign Patents Pending.

Manufacturer:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe AZ 85281
USA

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
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BARD PERIPHERAL VASCULAR

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Product Focus

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G2® Filter System

IFU | Ordering Info | Q&A Booklet

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G2® FILTER SYSTEM

INDICATED FOR RETRIEVAL

The G2® Filter quickly established its exceptional performance as a permanent vena cava filter with over 65,000 units sold worldwide.

NOW WITH THE OPTION OF EXTENDED RETRIEVAL, the G2® Filter gives physicians complete control over their patients' care.

- Increased MIGRATION RESISTANCE*
- IMPROVED CENTERING*
- Enhanced FRACTURE RESISTANCE*

*Data on File

Clot Trapping and Caval Patency

G2® Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation barbs, the newly enhanced G2® Filter resists migration across an even broader range of caval dimension and higher pressures.*

*Maximum indicated caval diameter is 28 mm. Data on File.

Easy to Use

Filter is completely loaded into the delivery system for easy assembly and delivery.

Self-Centering

Optically ultra-short pusher wire and articulated stem promote a centered IVC filter placement, even through tortuous anatomy.

G2 ® Filter System

G2® FILTER SYSTEM
for Permanent Placement

Tireless Performance

NOW AVAILABLE - JUGULAR DELIVERY SYSTEM

The G2® Filter combines the best design features of Bard's existing retrievable filters to create a brand-new permanent filter platform — delivering strength and stability to a new level.

The newly enhanced G2 ® Filter [illegible] Bard platform of filter innovation spanning over a decade.

- Increased MIGRATION RESISTANCE*
- IMPROVED CENTERING*
- Enhanced FRACTURE RESISTANCE*

*[illegible]

Clot Trapping and Caval Patency

G2 ® Filter utilizes the proven conical filter shape designed with two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2 ® Filter resists migration across an even broader range of caval dimensions and higher pressures.*

*[illegible]

Low Profile

7F delivery system is the lowest profile of any conical filter on the market.

Self-Centering

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

[illegible]

[illegible]

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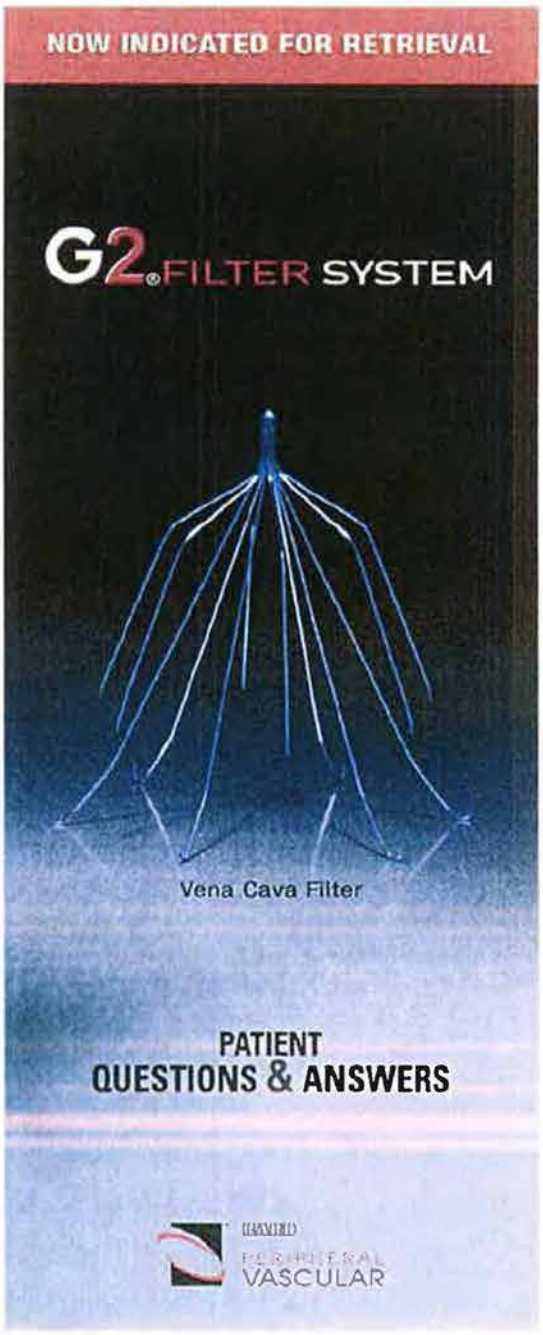
Vena Cava Filters

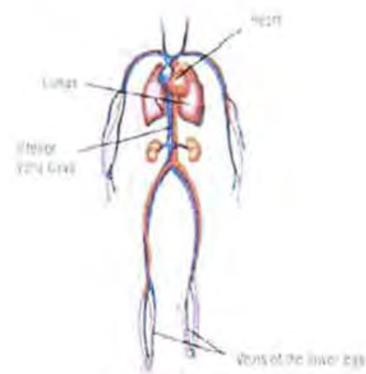
G2® Filter System

Product Code	Description	Units/Box
RF-310F	Femoral Delivery Kit	1
RF-320J	Jugular/Subclavian Delivery Kit	1


NOW INDICATED FOR RETRIEVAL
G2 FILTER SYSTEM
Vena Cava Filter
PATIENT
QUESTIONS & ANSWERS
BARD
PERIPHERAL
VASCULAR

PULMONARY EMBOLISM AND VENA CAVA FILTERS

Your doctor has given you this booklet to help you learn more about pulmonary embolism – what causes it, how it can affect your body and, most important, how it can be treated. After reading the booklet, talk to your doctor about any questions you have. It's important to remember that each patient is different and that only your doctor can give you information about the details of your specific treatment.



WHAT IS PULMONARY EMBOLISM AND WHAT CAUSES IT?

Pulmonary embolism is the condition that results when a blood clot forms, usually in the deep veins of the lower leg, and becomes loosened, traveling upward from the vein to the bloodstream. If not treated, there is a possibility that the clot may move up into the vessels that carry blood to the lungs. If this occurs, the normal functioning of the lungs may be impaired.

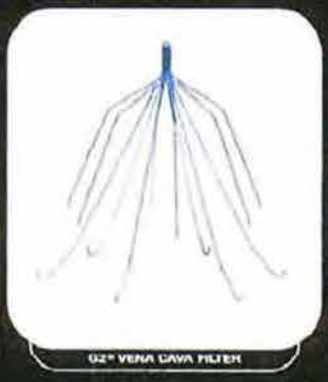
BPV-17-01-00137625
LMD1

WHAT TYPES OF TREATMENT ARE USED FOR PULMONARY EMBOLISM?

The most common treatment is a group of medications called anticoagulants or "blood thinners." However, there are some patients who, for a variety of medical reasons, cannot take anticoagulants. For these individuals, a vena cava filter may offer an effective treatment solution.

WHAT IS A VENA CAVA FILTER?

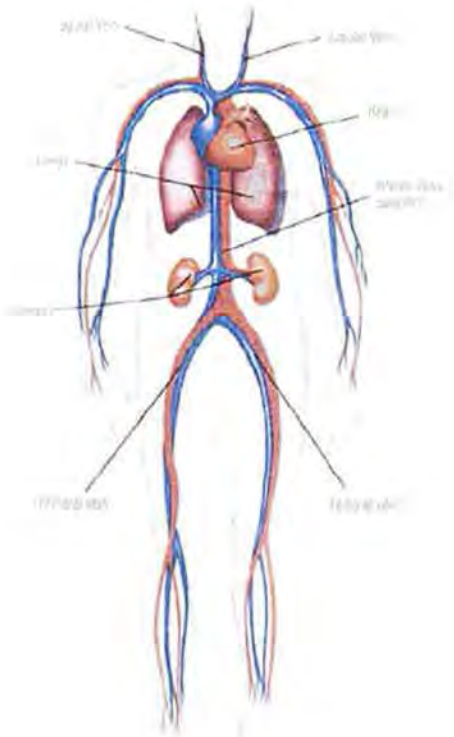
A vena cava filter is an expandable metal device specially designed to trap blood clots before they reach the lungs. The filter is placed in the inferior vena cava (IVC) – the large vein that carries blood from the lower extremities back to the heart and lungs – and remains in place to trap clots before they move further up toward the lungs.



02® VENA CAVA FILTER

THE IMPLANT PROCEDURE

The anatomical sites identified below will provide general guidance on those areas that are important in an implant procedure



HOW WILL THE FILTER BE INSERTED?

Your physician will insert the filter through either the right or left femoral vein in the upper thigh (see anatomical illustration on opposite page). To make the procedure as easy as possible, the filter is inserted inside a small plastic tube called a catheter. Once inserted, the filter expands to its predetermined shape and is held in place against the vena cava walls.

HOW LONG DOES THE PROCEDURE USUALLY TAKE?

Although it varies depending upon the individual patient and the specific circumstances, the implantation of the filter generally takes less than an hour.

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

Local anesthesia, plus a mild sedative that might be taken before the procedure, will normally result in little to no discomfort while the filter is being implanted.

HOW LONG WILL IT TAKE TO FULLY RECOVER?

Recovery from the procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc.

AFTER THE PROCEDURE

HOW LONG WILL THE FILTER LAST?

The G2® Filter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced.

CAN THE FILTER BECOME CLOGGED?

In the great majority of cases, the answer is "no." Once a clot becomes entrapped in the filter, the normal flow of your blood through the vena cava and the filter will usually dissolve a trapped clot as the blood flows over it.

IF I SHOULD NEED AN MRI EXAM, WILL THE METAL FILTER INTERFERE WITH THE TEST?

The G2® Filter is made from an alloy of nickel and titanium, and will not interfere with the test.

UNDER WHAT CIRCUMSTANCES SHOULD I CONTACT THE DOCTOR RIGHT AWAY?

You should contact your physician right away if you experience any of the following:

- sudden onset of chest pain accompanied by shortness of breath
- swelling in both legs
- unexplained pain in the abdomen

CAN THE FILTER BE REMOVED?

Yes. The filter can be removed when your physician determines that you no longer need it.

WHEN CAN THE FILTER BE REMOVED? IS THERE A "CUTOFF DATE" BY WHICH THE FILTER MUST BE REMOVED?

The G2® Filter does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to your physician.

REMOVAL PROCEDURE

HOW WILL THE FILTER BE REMOVED?

Your physician will remove the filter through either the right or left internal jugular vein (see anatomic illustration on page 4). He/she will insert a small tube called a catheter. Through the catheter, a grasping device will be advanced to the filter. The filter will be grasped, and then pulled into the catheter. Your physician will then remove the entire system together.

HOW LONG DOES THE RETRIEVAL PROCEDURE TAKE?

Although it varies depending upon the individual patient and the specific circumstances, the retrieval of the filter generally takes less than an hour.

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

As with the implant procedure, local anesthesia, helped by a mild sedative given before the procedure, will normally result in little to no discomfort while the filter is being removed. Afterwards, you may experience mild soreness in your neck for a few days. This is normal and will disappear. You will be left with a small scar on your neck at the puncture site.

HOW LONG WILL IT TAKE TO FULLY RECOVER FROM THE REMOVAL PROCEDURE?

Recovery from the removal procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc. Typically, you will be discharged several (2-3) hours after the procedure.

DOES THE FILTER HAVE TO BE REMOVED?

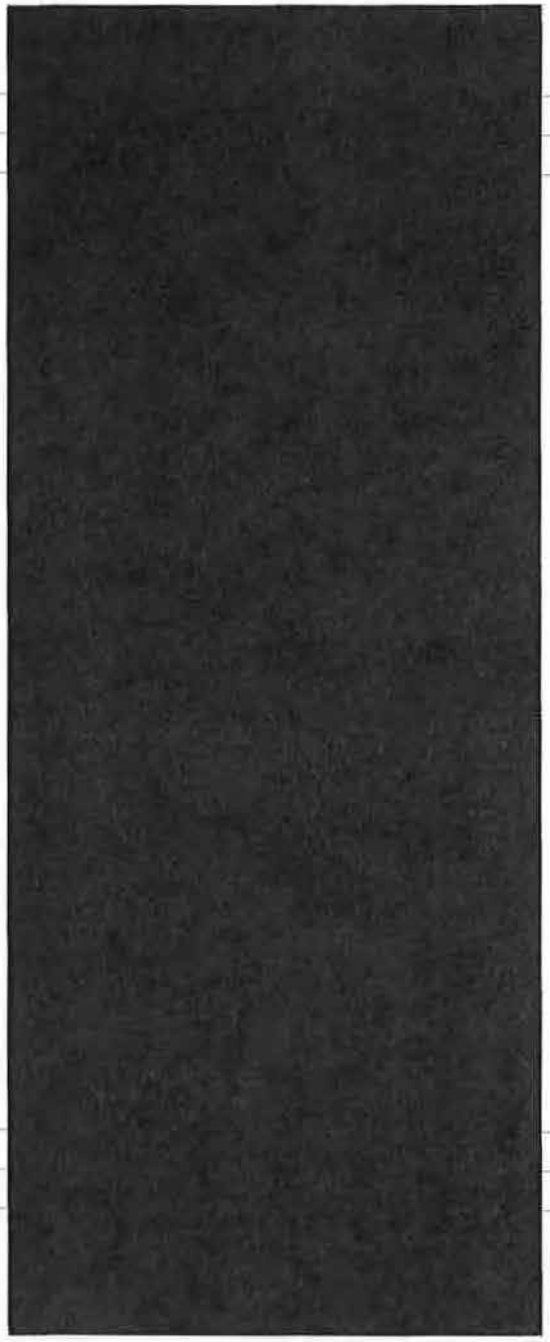
No. The G2® Filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced.

RESUMING YOUR NORMAL LIFESTYLE

SHOULD I RESTRICT MY ACTIVITIES AFTER THE FILTER IMPLANTATION OR REMOVAL PROCEDURE?

The implantation or removal of a vena cava filter is not necessarily a reason to restrict your normal activity level; **however**, each patient is unique and there may be other medical reasons for doing so. Be sure to discuss with your doctor what level of activity is most appropriate for you following the procedure.

NOTES:

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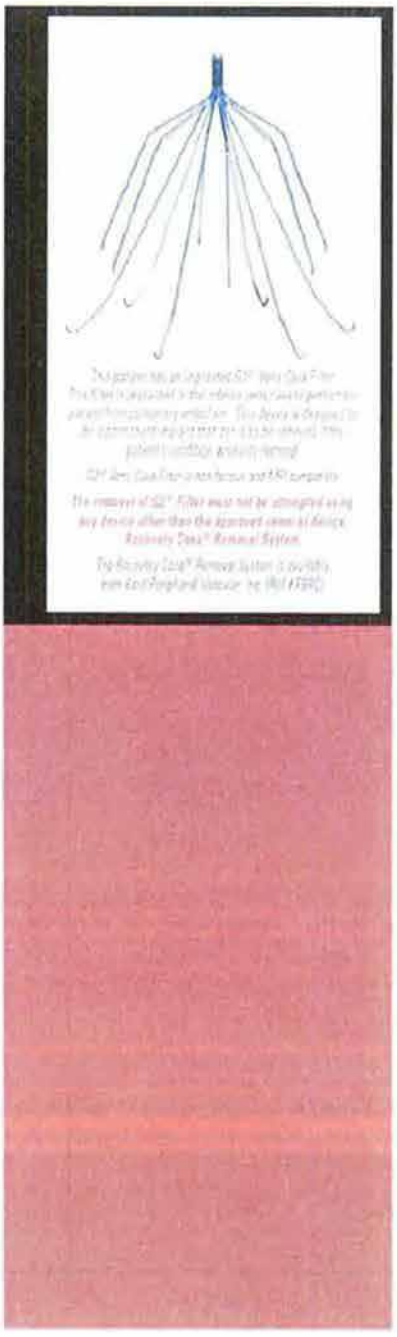
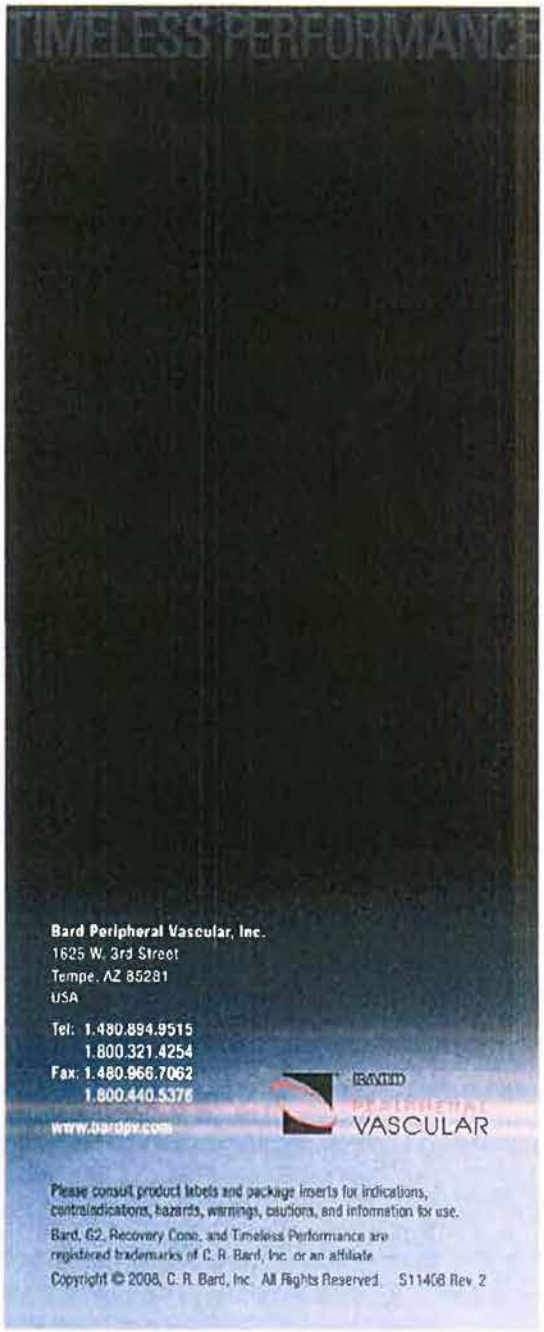
VASCULAR
Bard Peripheral Vascular, Inc.
Have your physician fill out this Patient Implant Card for you. Then, tear off at perforation and keep the card with you at all times.

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G2®
Filter System
Timeless Performance

G2® Filter System
Jugular/Subclavian Vein Approach
Instructions for Use

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ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The G2® Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the G2® Filter provide filtering efficiency and allow percutaneous placement through an angiographic introducer with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The G2® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The Jugular/subclavian system allows for placement of the G2® Filter via a jugular or subclavian vein approach. The Jugular/subclavian system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.038" guidewire and allows for an 800 psi maximum pressure contrast power injection. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the G2® Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to prevent leg entanglement. The G2® Filter is preloaded within the delivery device. Once the introducer sheath is within position, the delivery device is advanced through the introducer sheath until the introducer and delivery hubs snap together. The safety clip is then removed. The introducer hub is pulled back over the pusher wire handle to unsheathe and release the G2® Filter allowing it to recover to its predetermined shape.

The G2® Filter is designed to act as a permanent filter. When clinically indicated, the G2® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2® Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the G2® Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the G2® Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2® Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

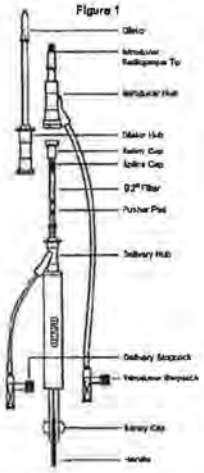
B. Device Description

The G2® Filter- Jugular/Subclavian System consists of the filter and delivery system. The G2® Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The G2® Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration.

The G2® Filter System -Jugular/Subclavian is illustrated in Figure 1. The Delivery System consists of a 10 French I.D. introducer sheath and dilator, the G2® Filter, and a delivery device. The G2® Filter is packaged pre-loaded within the delivery device.

Figure 1



IMPORTANT: Read instructions carefully before using the G2® Filter.

C. Indications for Use

The G2® Filter System- Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2® Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The G2® Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2® Filter Implantation

1. **The G2® Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2® Filter cannot be safely reloaded.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4).**
3. **If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.**
4. **Only use the *Recovery Cone*® Removal System to remove the G2® Filter. Never re-deploy a removed filter.**
5. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**
6. **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
7. **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
8. **Never use the jugular or subclavian delivery system for femoral approach, as this will result in improper G2® Filter orientation within the IVC.**
9. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.**

10. Persons with allergic reactions to nickel may suffer an allergic response to this implant.
11. After use, the G2® Filter system and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Reference Potential Complications section for further information regarding other known filter complications.

G2® Filter Removal

1. Do not attempt to remove the G2® Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall.
   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. Use only the Bard *Recovery Cone®* Removal System (packaged separately) to retrieve the G2® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.
3. Never re-deploy a removed filter.

F. Precautions

G2® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the G2® Filter using the *Recovery Cone®* Removal System Only. Refer to Optional Procedure for Filter Removal for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the G2® filter.
11. Do not remove the safety clip until the introducer and the delivery device hubs are snapped together.
12. Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the G2® filter.
13. It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.
14. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system.

G2® Filter Removal

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone®* Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the G2® Filter with the *Recovery Cone®* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the G2® Filter using the *Recovery Cone®* Removal System Only. Refer to the Optional Procedure for Filter Removal section for details.
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device.

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

- One G2® Filter Jugular/Subclavian System that contains:
  - -One 65 cm, 10 French I.D. introducer and dilator set
  - -One delivery device with pre-loaded G2® Filter
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18G entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to percutaneously remove the G2® Filter, the Recovery Cone® Removal System is available from C. R. Bard, Inc.

I. Directions for Use

1. Select a suitable jugular or subclavian venous access route, on either the right or left side, depending upon the patient's size/anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape, and anesthetize the skin puncture site in standard fashion.
3. Select and open the jugular/subclavian delivery system package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18G entry needle.
5. Insert a J-tipped guidewire and gently advance it into the inferior vena cava.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the 18G entry needle over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs snap together. Advance the 10 French introducer sheath together with its tapered dilator over the guidewire and into the inferior vena cava.

NOTE: A 0.035" guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

7. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 600 psi.

WARNING: If the vena cava diameter is greater than 28mm, do not deploy the G2® Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

8. Separate the dilator and introducer hubs by bending and then pulling apart (Reference Figure 2). Remove the guidewire and dilator, leaving the 10 French introducer sheath with its tip in the inferior vena cava. Flush intermittently by hand or attach to the introducer stopcock a constant saline drip infusion to maintain introducer patency.

Figure 2

9. Remove the delivery device from the package and remove the red safety cap (Reference Figure 3).

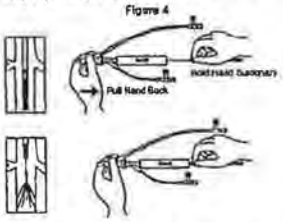
Figure 3

10. Flush the delivery device with saline through the delivery stopcock.
11. Insert and advance the delivery device through the introducer sheath until the introducer and delivery device hubs snap together (Reference Figure 4).

PRECAUTION: Ensure that the introducer and the delivery device hubs are snapped together and that the system has been positioned for optimal placement, before deploying the G2® filter.

NOTE: Do not remove the safety clip until step #13.

Figure 4



12. Under fluoroscopic control, position the system for optimal placement. The distal end of the pusher pad provides the radiopaque indicator for positioning purposes (Reference Figure 5).

NOTE: Do not remove the safety clip until step #13.

Figure 5

NOTE: A gap between the filter apex and pusher pad is normal.

13. Remove the safety clip from the delivery device.
14. Stabilize the handle and pull back on the introducer hub (blue) to retract both the introducer sheath and delivery device. Retract the introducer hub until the handle bottoms out against the proximal edge of the delivery catheter hub (white). This will release the G2® filter into position (Reference Figure 6).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the G2® filter.

Figure 6

15. Separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.
16. Perform a venacavogram to confirm satisfactory deployment before terminating the procedure.
17. Remove the introducer sheath and apply routine compression over the puncture site in the usual manner to achieve hemostasis.

(3)

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2® Filter using the *Recovery Cone*® Removal System only.

Removal of G2® Filter

Equipment Required

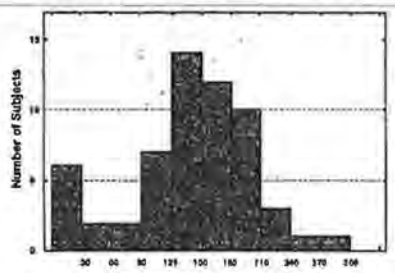
The following equipment is required for use.

- One *Recovery Cone*® Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with *Recovery Cone*® and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the G2® Filter. 81 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 81 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis. The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 7 depicting the time to retrieval.

Figure 7: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 81 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the *Recovery Cone*® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the *Recovery Cone*® Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the G2® Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the G2® Filter.

***Recovery Cone*® Removal System Insertion and Delivery**

11. Remove the *Recovery Cone*® Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker at the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

Filter Removal, Illustrated

17. The capture of the G2® Filter is illustrated in Figures A-E:

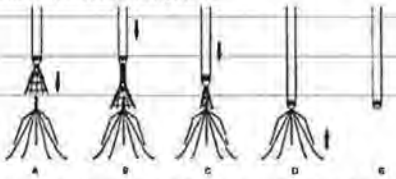


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to ensure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the G2® Filter, guidewire-assisted techniques may be used.

If it is difficult to align the cone with the G2® Filter tip, a guidewire could be used to facilitate advancement of cone over the filter tip. Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip. After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the filter tip. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each G2® Filter is supplied preloaded in a delivery device. Each G2® Filter system is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

WARNING: After use, the G2® Filter system and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The G2® Filter system should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- "Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" (ACR Practice Guideline 2007; 30:673-684)
- "American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" (Chest 1998 Feb; 113(2): 499-504)
- "Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" (J Trauma 2002; 53:142-614)
- "Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" (JVIR 2003; 14:S271-S275)

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter After Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grenda, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2006, 99(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.


G2® Filter


G2® Filter System Jugular/Subclavian Delivery Device


G2® Filter System Introducer Sheath With Dilator


Jugular/Subclavian


Use By


Lot Number


Catalog Number


Attention, See Instructions for Use


Sterilised By Using Ethylene Oxide


Non-pyrogenic


Keep Dry


Protect From Heat


Single Use


Do Not Restarilize


Do Not Use If Package Is Damaged Or Opened.


MR Conditional


Contents:
G2® Filter Jugular/Subclavian Delivery Device
10 Fr. Introducer Sheath 55cm Long with Dilator


Recommended Guidewire


Manufacturer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Variously Protected by one or more of the following U.S. Patent Numbers: 6,007,558 and 6,258,026. Other U.S. and foreign Patents Pending.

Manufacturer:
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BARD
PERIPHERAL
VASCULAR

PK5280600 Rev. 1 07/09

G2® Filter System

Timeless Performance

G2® Filter System

Femoral Vein Approach

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The G2® Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the G2® Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the G2® Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The G2® Filter is designed to act as a permanent filter. When clinically indicated, the G2® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2® Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the G2® Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.6 W/kg for 20 minutes of scanning.

In non-clinical testing, the G2® Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

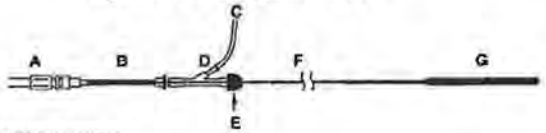
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2® Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

B. Device Description

The G2® Filter System - Femoral consists of the filter and delivery system. The G2® Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The G2® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The G2® Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the G2® Filter, a storage tube with saline infusion port, and a pusher system. The G2® Filter is packaged pre-loaded within the delivery storage tube.

Figure A. G2® Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the G2® Filter

C. Indications for Use

The G2® Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2® Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

D. Contraindications for Use

The G2® Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2® Filter Implantation

1. **The G2® Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2® Filter cannot be safely reloaded into the storage tube.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)**
3. **Delivery of the G2® Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.**
4. **The G2® Filter System - Femoral is designed for femoral approaches only. Never use the G2® Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2® Filter orientation within the IVC.**
5. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.**
6. **Only use the *Recovery Cone*® Removal System to remove the G2® Filter. Never re-deploy a removed filter.**
7. **Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.**
8. **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
9. **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
10. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
11. **After use, the G2® Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

G2® Filter Removal

1. **Do not attempt to remove the G2® Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena cava wall.**

   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. **Use only the Bard *Recovery Cone*® Removal System (packaged separately) to retrieve the G2® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.**
3. **Never re-deploy a removed filter.**

F. Precautions

G2® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the G2® Filter using a *Recovery Cone*® Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
12. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
13. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

G2® Filter Removal

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone*® Removal System. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the G2® Filter with the *Recovery Cone*® Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the G2® Filter using the *Recovery*® *Cone* Removal System Only. (Reference Optional Procedure for Filter Removal for specific removal instructions).
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2006; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One G2® filter and Delivery System that contains:
  - One 48cm, 7 French I.D. introducer catheter and dilator set
  - One Storage tube with pre-loaded G2® Filter and pusher delivery system
- 0.038" 3mm J-tipped Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: Scalpel, #11 blade, local anesthesia, drapes, etc

If the physician chooses to percutaneously remove the G2® Filter, the *Recovery Cone*® Removal System is available from C.R. Bard, Inc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

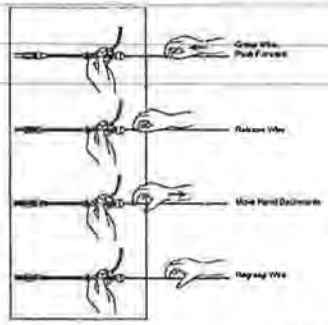
Advancement of G2® Filter, Illustrated

Figure A

Figure B

Figure C

Figure D



13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

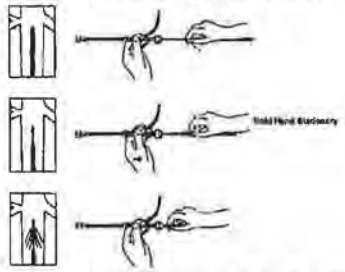
Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated

FIGURE E
FIGURE E-1

FIGURE F
FIGURE F-1

FIGURE G
FIGURE G-1



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tub assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2® Filter using the *Recovery Cone*® only.

Removal of G2® Filter

Equipment Required

The following equipment is required for use:

- One *Recovery Cone*® Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with *Recovery Cone*® and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium

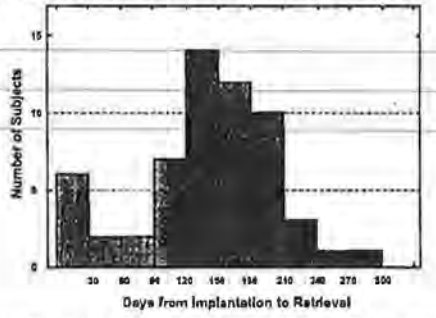
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the G2® Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time to retrieval.

Figure H: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the *Recovery Cone*® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the *Recovery Cone*® Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the G2® Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 16 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the G2® Filter.

***Recovery Cone*® Removal System Insertion and Delivery**

11. Remove the *Recovery Cone*® Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

17. The capture of the G2® Filter is illustrated in **Figures A-E**:

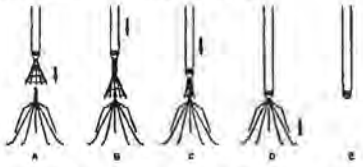


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the G2® Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the G2® Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended).

Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17.

J. How Supplied

Each G2® Filter is supplied preloaded in a storage tube. Each G2® Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Warning: After use, the G2® Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The G2® Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:873-884]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hegspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.

G2® Filter System

FEM Femoral

FIC Femoral Introducer Catheter

Use By

LOT Lot Number

REF Catalog Number

Attention, See Instructions for Use

STERILE EO Sterilized By Using Ethylene Oxide

NON PYROGENIC Non-pyrogenic

Single Use.

Do Not Resterilize.

Do Not Use If Package Is Damaged Or Opened.

MR Conditional

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 46cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System

Protect From Heat

Keep Dry

Recommended Guidewire

Manufacturer:

Bard, G2®, *Recovery Cone*® and Timeless Performance are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Variously protected by one or more of the following U.S. Patents: 8,007,568 and 6,258,026. Other U.S. and Foreign Patents Pending.

Manufacturer:
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Tempe, AZ 85281
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1-800-321-4254
FAX: 1-480-968-7052
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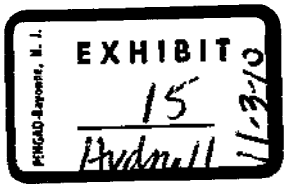
BARD PERIPHERAL VASCULAR

PK5250500 Rev. 1 07/09

EXHIBIT EE

3. POA



Document Detail

ument No: POA-7081
Document Title: Product Opportunity Appraisal for Recovery Filter System
Document Version: 000
Release Date: 3/28/2003 08:39:06
Description:
Product Opportunity Appraisal for Recovery Filter System

Release Panel:
Werner Tia
Shifrin Kevin
Carr Robert
DeCant Len
Dejohn Joe
Edwards Mary
Hudson Brian
Krueger Bill
McDermott John

Files:
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BPV-15-01-00120460

Bard Division: BPV
Project Name: Recovery
Project Number: 7081
Product Line: Filters
Team Leader: Rob Carr **Marketing Representative:** Janet Hudnall

Timing and Status:

	Start Date	End Date	Approval Date to Enter Next Phase
Phase 0- Concept / Feasibility			
Phase 1- Design & Development			
Phase 2- Design Qualification			
Phase 3- Process Qualification & Clinicals			
Phase 4- Market Release			

1. Executive Summary

Project Type and Duration (please mark only one box)

☒	New Product Development	☐	Distribution Agreement
☐	Enabling Technology	☐	CIP

Estimated Project Duration, Phase 1 through Launch (phase 3) months

Summary Project Description. Include a brief overview of the product/ CIP/ transfer, the opportunity and business rationale.

The purpose of this project is to develop and commercialize a permanent IVC filter that is also removable after an extended period of implantation.

Venous thrombosis and pulmonary embolism constitute major health problems that result in significant morbidity and mortality. In the U.S. alone, it is estimated that venous thrombosis and pulmonary embolism contribute to 600,000 hospitalizations per year and that as many as 150,000 individuals die each year as a result of pulmonary embolism. Patients with various types of diseases, especially certain cancer patients, are at high risk for developing deep venous thrombosis (DVT) and pulmonary embolism (PE). Patients undergoing surgery (especially orthopedic, ob/gyn, urological, and neurosurgical) are also at high risk for venous thrombotic events. The standard treatment for people with thromboembolic disease is anticoagulation therapy. Current indications for percutaneous inferior vena cava (IVC) filter placement include patients with PE that cannot tolerate anticoagulation. In addition, IVC filters are increasingly being placed prophylactically in patients who are contraindicated for, or unresponsive to, anticoagulation. This includes patients at high risk of developing PE but who have not yet developed symptoms and patients with venous thrombosis, but without concomitant PE. It is widely believed that a temporary (or removable) filter might be a better option for prophylactic use and for patients with short-term contraindications to anticoagulation. Possible patient populations include young patients who require protection from PE but in whom doctors are disinclined to place a permanent cardiovascular implant.

Key Project Financials

$2.4M 1st Yr Rev.s (incremental) $25.5M 3rd Yr Rev.s (incremental)

$25.2M NPV	$870,000 R&D Budget

2. Market / Customer / Device

Market Description. Include market definition, trends and opportunities as well as any segmentation information.

The current U.S. IVC Filter market totals $114MM. The market leader as of October, 2002 is the TrapEase (Cordis Corp) with a 40% share. Long regarded as the "gold standard" for caval interruption, the Greenfield (Boston Scientific) has suffered from the introduction of TrapEase in July, 2000. The availability of a new filter, Gunther Tulip (Cook, Inc.), with its implied removability, has further negatively affected Greenfield's share. In addition to taking share away from Greenfield, the Gunther Tulip has also contributed to the growth of the entire filter market (which had been relatively flat for some time) by 17% between October, 2001 and September 2002. Bard's Simon Nitinol Filter has maintained its market share position at 11-12% despite the introduction of new products; however, we will need to introduce a new device with clear advantages in order to maintain and grow our IVC filter business moving forward.

The following points summarize the current IVC Filter market and project the future trends:

- Although the filter market is a mature one, it is still dynamic and susceptible to dramatic shifts when new devices and/or indications are introduced.
- Users can be swayed by ease of use, low profile, and aggressive marketing even in the absence of solid clinical history and in spite of documented negative clinical experiences.
- Optional/temporary filters will create a new category and expand the entire filter market.
- The majority of the growth in the vena cava filter market will come from the optional filter segment.
- Customers desire a filter that is durable enough to be a permanent filter, yet offer the flexibility of being able to be removed whenever the physician decides that mechanical caval interruption is no longer needed to protect the patient from a fatal PE.

Customer Requirements. Include performance, physical requirements, safety considerations, price tolerance, packaging requirements, special requirements for international markets and desired marketing claims (please reference sources)

Filter

- Must be designed so that it can be safely removed after an extended period of indwelling time.
- Exhibit clot-trapping efficiency comparable to currently available filters.
- Visible under fluoroscopy.
- Resist migration.
- MRI safe and compatible.
- Exhibit minimal tilting within the vena cava.
- Filter legs should not cross upon deployment.

Delivery System

- Flexible enough to navigate through tortuous anatomies associated with a left femoral introduction
- Allow safe and accurate delivery of the device into the intended location.
- Low profile (≤7F ID)
- Facilitate delivery of the filter in a centered manner.

Packaging

- Adequately protect the device, yet be easy to store and handle.

Device Description If complete description (including materials, performance & features) is contained in an attached Design Document, feel free to reference. Description should match Project Profile

- Nitinol construction.
- Dual-level filter with 6 "arms" & 6 "legs"
- Designed for 28mm maximum caval diameter
- Each filter shall be loaded into a 7F ID/9F OD delivery system designed for left or right femoral vein introduction.
- Refer to Product Performance Specification (PPS) for complete description.

3. Competitive Analysis

Summarize key aspects of existing and potential competitor offerings.

Competitor & Product Name	Date on Market	Est. U.S. Market Share ($)	ASP*	Strengths & Weaknesses from Performance/Feature Standpoint
Boston Scientific (MediTech) Greenfield	1956	25%	$985	S: Regarded as the "gold standard" of IVC filters. Extensive clinical history. W: Large profile, single level of filtration, tendency to tilt
Cook Gunther Tulip	Oct, 2000	12%	$1,075	S: Extensive O.U.S. experience. First on the market with implied removability. W: Short implantation time (14 days). Single level of filtration. Tendency to tilt. Delivery & removal are not user-friendly.
Cordis TrapEase	Jun, 2001	20%	$1,092	S: Lowest profile device on the market. easy to use, only one system needed for both femoral and jugular introduction. W: Many reported complications, questionable filter design
Cordis OptEase	Oct, 2002	13%	TBD	S: TrapEase market position. W: Short implantation time (12 days in Europe), femoral removal may not be ideal for certain patient populations. Price.
B.Braun Venatech	1989	6%	$950	S: "Dual Filter" – decreased inventory requirement W: Predicate device's history of guidewire entrapment; can be confusing, possibility of placing filter upside down.
Proposed Product ** *(est.)*	Apr, 2003	19%	$1,300	S: First and only permanent filter that can be removed beyond two weeks after implantation. Proven conical shape. Two-level filtration. Low profile. W: only available in femoral delivery, larger profile than Cordis filters

* Average Selling Price

** Use estimated market share % for year 3

Competitive Analysis. Competitive assessment & assumptions including an analysis of competing/alternate technologies if appropriate.

There is currently no removable vena cava filter available in the U.S. Clinical, Animal, and Bench data to date show that this product will most likely be indicated for removal well beyond the 12-14 day range that the competition is currently pursuing. This, in conjunction with the merits of its design as a caval filtration device, give Recovery a significant competitive edge.

Patents. Describe patent positions and strategy. If a complete description is contained in an attached Design Document, feel free to reference.

6,007,558 and 6,258,026

4. Market Positioning & Timing

Product Positioning. Include price, performance & feature benefits to customer. Call point info & any training or reimbursement issues should be addressed as well.

Positioning: The first and only permanent filter that can be removed beyond 14 days after implantation.

List Price: $1,395 ea.

Features (Benefits)

- Nitinol Construction
- Leg Spline
- Flex Hinge
- Two-level filtration
- Arms down design
- Elastic Hooks

Call point: Interventional Radiologist, Vascular Surgeon, General Surgeon, Trauma Surgeon

Training: each physician should be thoroughly in-serviced by the sales representative prior to placing/removing the Recovery Filter

Reimbursement
Placement: 36010 - IVC catheter, 75825 - IVC gram, 37620 -Interruption, partial or complete, of IVC
Removal: 36010 - IVC catheter, 75825 - IVC gram, 37203 & 75961 - foreign body retrieval

There is currently no CPT code specifically for IVC filter removal.

Market Timing and Launch Strategy. Describe U.S. versus international launch plan. If LMR is planned, include rationale.

U.S.

Market introduction will occur in 2 phases:

Permanent indication

LMR is necessary for two reasons: 1) manufacturing capacity 2) targeting customers that will not attempt removals

Strategy: Take as much share as possible, Drive Recovery to be standard in caval interruption, and Grow the market

Removable indication

Launch objective will be to dispel the segmentation that has been created in the market place between "permanent" and "removable" indications.

International

LMR to begin with U.K. (objectives: gain additional clinical experience, glean positioning/targeting information, manage downside risk of potential adverse events prior to U.S. regulatory clearance for removable indication)

Market release will occur by each country once the BCs provide a marketing plan including an analysis of the opportunity and business rationale for commercialization.

Cannibalization. List current products that will be cannibalized or made obsolete by this product and quantify the impact

Simon Nitinol Filter

Year 1 – $2M

Year 2 - $7M

Year 3- $9M

5. Clinical and Regulatory

U.S. Please mark applicable

☐ No File Rationale	☐ PMA Supplement	☐ IDE Clinical Feasibility
x 510 (k)	☐ PMA	☐ IDE

Describe and comment on level and timing of activity

European. Please mark applicable

X CE Mark	☐ Self Certification	☐ Clinical Feasibility	☐ Type Testing

Describe and comment on level and timing of activity

Device already CE Marked at time of this report

6. Financial Opportunity *(Complete the following information in a spreadsheet/financial model)*

U.S. Market	Yr.1	Yr.2	Yr.3	Yr.4	Yr.5
Market Size ($)	$ 113,000,000	$ 129,865,672	$ 142,852,239	$ 157,137,463	$ 172,851,209
ASP	1,005	1,050	1,050	1,050	1,050
Market Size (units)	112,438	123,682	136,050	149,655	164,620
Growth		10%	10%	10%	10%
BPV:					
Market Share	3.00%	13.00%	19.00%	23.00%	25.00%
ASP	1275	1325	1300	1300	1275
Units	3,373	16,079	25,849	34,421	41,155
Total Revenue ($)	$ 4,300,746	$ 21,304,154	$ 33,604,289	$ 44,746,763	$ 52,472,688
Cannibalized Rev.	$ 2,000,000	$ 7,000,000	$ 9,000,000	$ -	$ -
Incremental Rev.	$ 2,300,746	$ 14,304,154	$ 24,604,289	$ 44,746,763	$ 52,472,688
Target cost (unit)	504.125	514.875	509.5	509.5	504.125
Target cost (total)	$ 1,700,481	$ 8,278,473	$ 13,170,296	$ 17,537,289	$ 20,747,289
Target Gross Margin (unit)	$ 770.88	$ 810.13	$ 790.50	$ 790.50	$ 770.88
Target Gross Margin (total)	$ 2,600,265	$ 13,025,681	$ 20,433,992	$ 27,209,474	$ 31,725,399
Est. Gross Profit (Incr.units only)	$ 1,391,049	$ 8,745,776	$ 14,961,300	$ 27,209,474	$ 31,725,399

*If a specific launch date is assumed. Year 1 will only have sales for that calendar year.

Notes:

Assumes launch April, 2003 with permanent indication

Does not include the Recovery Cone

25% of revenue projected to come from Jugular/Subclavian/Antecubital delivery options starting Yr. 2

Int'l Market	2003	2004	2005	2006	2007
Market Size ($)	$ 20,000	$ 21,000,000	$ 22,050,000	$ 23,152,500	$ 24,310,125
ASP	1,000	1,000	1,000	1,000	1,000
Market Size (units)	20,000	21,000	22,050	23,153	24,310
Growth		9%	10%	9%	8%
BPV:					
Market Share	0.5%	2.3%	4.2%	6.5%	9.4%
ASP	1000	1000	1000	1000	1000
Units	105	491	930	1,515	2,276
Total Revenue ($)	$ 105,000	$ 491,000	$ 930,000	$ 1,515,000	$ 2,276,000
Cannibalized Rev.	$ -	$ -	$ -	$ -	$ -
Incremental Rev.	$ 105,000	$ 491,000	$ 930,000	$ 1,515,000	$ 2,276,000
Target cost (unit)	445	445	445	445	445
Target cost (total)	$ 46,725	$ 218,495	$ 413,850	$ 674,175	$ 1,012,820
Target Gross Margin (unit)	$ 555.00	$ 555.00	$ 555.00	$ 555.00	$ 555.00
Target Gross Margin (total)	$ 58,275	$ 272,505	$ 516,150	$ 840,825	$ 1,263,180
Est. Gross Profit (Incr.units only)	$ 58,275	$ 272,505	$ 516,150	$ 840,825	$ 1,263,180

Notes:

Does not include Recovery Cone

25% of revenue projected to come from Jugular/Subclavian/Antecubital delivery options starting Yr. 2

Note: Global Market is the summation of the above U.S. and International forecasts

Global Market	Yr.1	Yr.2	Yr.3	Yr.4	Yr.5
Market Size ($)	$ 113,020,000	$ 150,865,672	$ 164,902,239	$ 180,289,963	$ 197,161,334
ASP					
Market Size (units)	132,438	144,682	158,100	172,807	188,930
Growth					
BPV:					
Market Share (units)	3%	11%	17%	21%	23%
ASP	1267	1315	1290	1287	1261
Units	3,478	16,570	26,779	35,936	43,431
Total Revenue ($)	$ 4,405,746	$ 21,795,154	$ 34,534,289	$ 46,261,763	$ 54,748,688
Cannibalized Rev.	$ 2,000,000	$ 7,000,000	$ 9,000,000	$ -	$ -
Incremental Rev.	$ 2,405,746	$ 14,795,154	$ 25,534,289	$ 46,261,763	$ 54,748,688
Target cost (unit)	502	513	507	507	501
Target cost (total)	$ 1,747,206	$ 8,496,968	$ 13,584,146	$ 18,211,464	$ 21,760,109
Target Gross Margin (unit)	$ 764.36	$ 802.56	$ 782.32	$ 780.57	$ 759.56

Target Gross Margin (total)	$ 2,658,540	$ 13,298,186	$ 20,950,142	$ 28,050,299	$ 32,988,579
Est. Gross Profit (Incr.units only)	$ 1,451,689	$ 9,027,177	$ 15,490,314	$ 28,050,299	$ 32,988,579

Notes:

Does not include Recovery Cone

25% of revenue projected to come from Jugular/Subclavian/Antecubital delivery options starting Yr. 2

7. Project Cost

Note: For approval to move from Concept Investigation to Feasibility, summary estimates of costs for the entire program and detailed estimates for the next phase are required

For approval to move from Feasibility to Development, detailed estimates for the entire project are required. If these costs are outlined in Operating Plan (PDOP, PROP) please reference.

	Expense	Notes:
R&D- Labor (hours and rates)	240,000	
R&D Materials	100,000	
Capital- Tooling & Equipment	800,000	
Clinical	500,000	50 patients, 4 sites
Packaging	30,000	Carton graphics, tooling for new tray design, packaging engineer labor
Regulatory	50,000	240 hours - two 510(k)s @ 80 hours; 80 additional hours for planning regulatory strategy and miscellaneous communication with FDA
Marketing - Product Launch (Promotions, Literature)	350,000	Hands-on workshops, brochure, animation,
Marketing - Other (i.e., IFU translations)	100,000	
TOTAL	$2.17 M	

8. Business Rationale/ Strategic Fit

Address the business/strategic gains this project offers from both the product line and overall business standpoint. Please reference the Strategic Impact category and the Strategic Alignment score.

Strategic Alignment Score: 2

Strategic Impact Category: Innovation Leader

The Recovery Filter will give Bard an opportunity to take a leadership position in the Vena Cava Filter market. Clinical, Animal, and Bench data to date show that this product will most likely be indicated for removal well beyond the 12-14 day range that the competition is currently pursuing. This, in conjunction with the merits of its design as a caval filtration device, give Recovery a significant competitive edge.

Offering a product that is so far ahead of the competition in terms of its ability to meet a previously unmet clinical need will position Bard as an innovator that is knowledgeable and concerned about the market, the disease state, and the needs of the customer. We will be able to leverage this image to gain business in other product lines as well as position us for future product introductions.

9. Resources

Include project team member names and allocations to this project

Function	PHASE 1: Concept Investigation	PHASE 2: Feasibility	PHASE 3: Development & Clinicals
Marketing			Janet Hudnall
R&D			Rob Carr
Manufacturing			Frank Madia (GFO)
Quality			L. Buchanan Kopp & B. Hudson
Clinicals			Rob Righi
Regulatory			Mary Edwards
Materials / Ops			Rhonda Peck
Finance			Janet Fillinger

Attachments

1. Project Profile (including resource demand forecast)
2. Financial Model